

# INSTRUCTIONS FOR USE

Enbrel® MYCLIC® pre-filled pen



(not actual size)

**Enbrel**  
Etanerceptum

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# PREFACE

Dear Patient,

Your doctor has already given you information on the technical use of the MYCLIC® pre-filled pen. We also recommend you read the package leaflet and these instructions carefully before you use the MYCLIC® pre-filled pen for the first time. The instructions will take you through injecting yourself, step by step, and show you how using Enbrel® (etanercept) can become part of your daily routine with a little practice.

Please ask your doctor, pharmacist or nurse if you have any further questions on the preparation and injection of Enbrel® after you have read the package leaflet and these instructions.

**Please carefully read through the entire instructions on the steps for using the MYCLIC® pre-filled pen**

- 1 Preparing the injection
- 2 Selecting the injection site
- 3 Injecting the Enbrel® solution
- 4 Disposing of the materials

## WHAT YOU SHOULD BE AWARE OF BEFORE USE

Store the Enbrel® MYCLIC® pre-filled pen in the **refrigerator at between 2 and 8 °C**, do not freeze and store in the original packaging to protect the contents from light. Enbrel® can be stored at room temperature (up to a maximum of 25 °C) for a single time period of up to 4 weeks. Enbrel® that has not been used within 4 weeks after removing from the refrigerator and storing at 15–25 °C should no longer be used. Enbrel® must not be refrigerated again once it has been removed from the refrigerator. Furthermore, this brochure is based on the assumption that Enbrel® is stored at a temperature of 2–8 °C.

**Only** use the MYCLIC® pre-filled pen or other materials associated with the injection **once**. Keep the place where you will be carrying out the injection and the injection materials you need **as clean as possible**.

**Do not use Enbrel® after the expiry date** which is printed on the folding box and the pre-filled pen.

It may be helpful to **set a specific day** (also 2 days a week, depending on the dose regimen) and **a specific time** for the injection.

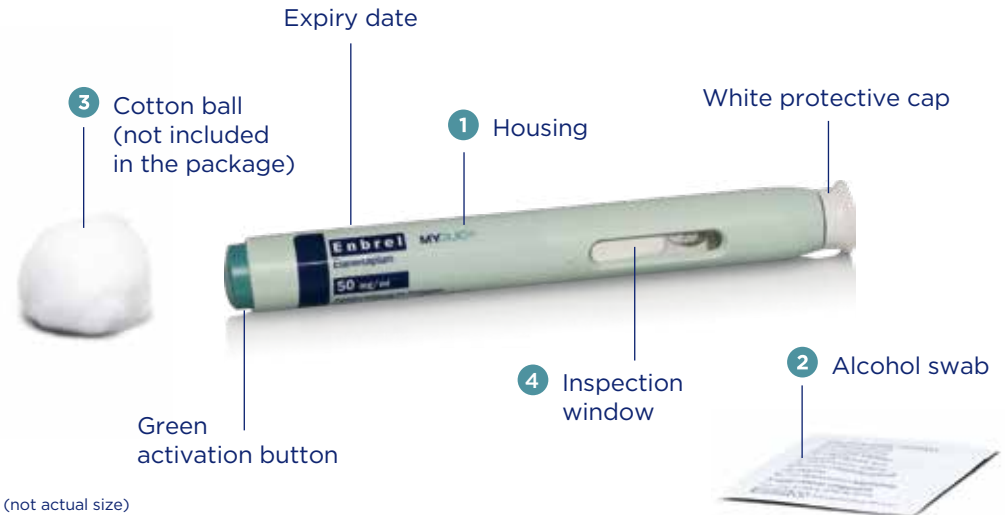
**Dispose of the MYCLIC® pre-filled pen** as instructed by your doctor, pharmacist or nurse.

### **Before you inject Enbrel® with the MYCLIC® pre-filled pen**

Read the package leaflet carefully before you use the MYCLIC® pre-filled pen – it contains important information for you.

Please ensure that **the pre-filled pens are kept out of the reach of children**.

# HOW TO USE THE MYCLIC® PRE-FILLED PEN



The instructions below explain how to use the MYCLIC® pre-filled pen to inject Enbrel® (etanercept). Please read these instructions carefully and follow them step by step. Your doctor will show you beforehand how to inject Enbrel®. Do not try to carry out an injection if you are unsure you have fully understood how to use the MYCLIC® pre-filled pen correctly.

**Please ask your doctor, pharmacist or nurse for help if you have any questions on how to administer the injection.**

## STEP 1 Preparing the injection

1

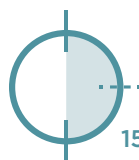
Take the Enbrel® package with the MYCLIC® pre-filled pen out of the refrigerator. Remove a pre-filled pen from the package and place it on a flat work surface.

**Do not shake the MYCLIC® pre-filled pen.** Put the package with the second pre-filled pen back into the refrigerator.

Check the expiry date given on the label of the MYCLIC® pre-filled pen. It should no longer be used after the expiry date (month and year).

**Wait for about 15 to 30 minutes** until the MYCLIC® pre-filled pen has reached room temperature. **Do NOT remove the white protective cap during this time!** **Do NOT warm the MYCLIC® pre-filled pen in any other way** (e.g. in the microwave or in hot water). This injection must not be mixed with other medicinal products.

Select a clean, well lit and flat work surface.



15-30 min

**Wait for about 15 to 30 minutes** until the MYCLIC® pre-filled pen has reached room temperature



(not actual size)

Lay the material required for the injection out on the work surface:

- 1 one MYCLIC® pre-filled pen
- 2 one alcohol swab
- 3 one cotton ball or gauze  
(not included in the package)

Check the solution in the MYCLIC® pre-filled pen inspection window 4. **Make sure that the solution in the pre-filled pen is clear to opalescent, and colourless to yellow or pale brown. It may contain traces of translucent to white amorphous (i.e. with no structure) particles.**

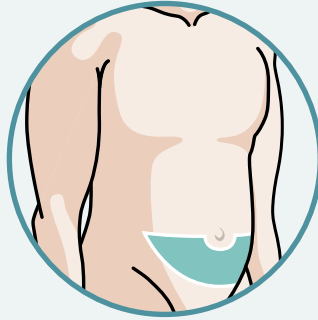
Do not use the solution if its colour differs from the above or if it contains lumps, flakes or any particles other than those described here. In such cases, contact your doctor, pharmacist or nurse.

## STEP 2 Selecting the injection site

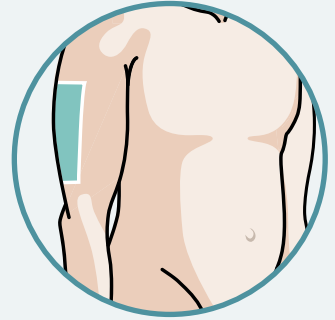
# 2



Thigh



Stomach



Upper arms

**The recommended injection site is the middle of the front of the thigh.** If you prefer your stomach as the injection site, please ensure that the injection site is located at least 5 cm from the navel. The outside of the upper arms can also be selected if another person is giving you the injection.

**Making a list will help you to remember recent injection sites.**

Each new injection should be administered at a different site, at least 3 cm away from the last injection site. Do not inject into sensitive skin, skin that is red or hard, or into bruises. Avoid portions with scars or stretch marks.

Psoriasis patients should try to select an area of skin that is not raised, thickened, red or scaly.



## Injecting the Enbrel® solution

### STEP 3

# 3

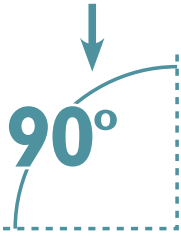


Wash your hands thoroughly with soap and warm water after you have waited for at least 15 minutes for the solution in the MYCLIC® pre-filled pen to reach room temperature.

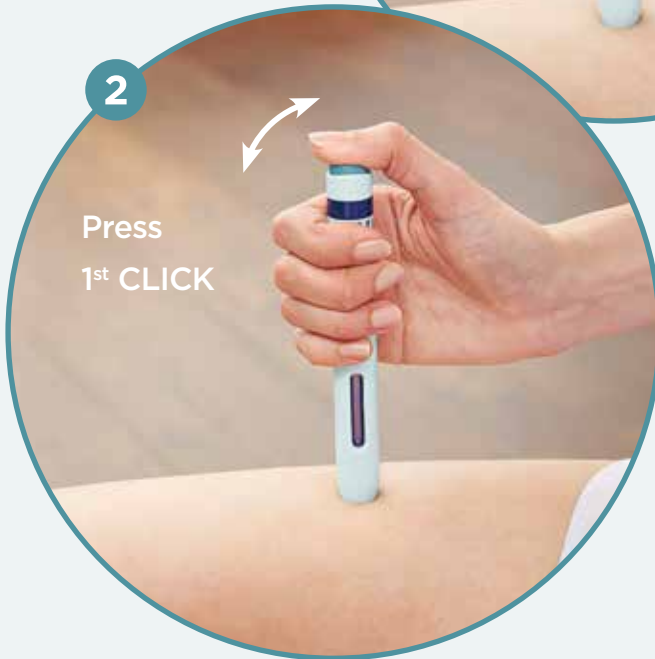
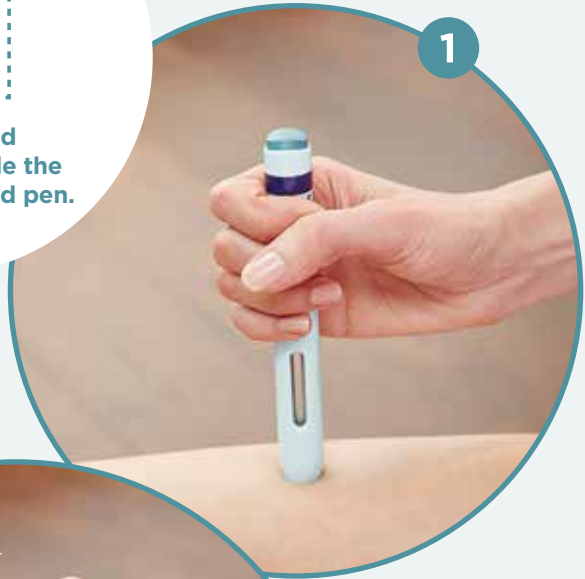
**Clean the injection site with the alcohol swab** using circular movements and allow it to dry. Do not touch the injection site again.

Once the skin is dry, take the MYCLIC® pre-filled pen and remove the white protective cap by pulling it forward. You will see the purple needle guard that protrudes slightly from the end of the pre-filled pen once you have removed the white protective cap. Do not use the pen if it has fallen on the floor after you have removed the protective cap.

To avoid damaging the needle inside the MYCLIC® pre-filled pen, **do not bend the white protective cap while pulling it off and do not put it back on once it has been removed.**



Needle guard  
disappears inside the  
MYCLIC® pre-filled pen.



## STEP 3 Continued

# 3

- 1 Without pressing the green button on the top of the MYCLIC® pre-filled pen,** hold the MYCLIC® pre-filled pen at a right angle (90°) to the injection site and press the open end of the MYCLIC® pre-filled pen firmly over the needle guard until it is no longer visible. This will produce a slight indentation in the skin. Lightly pressing the skin together between the thumb and index finger of your free hand in the area of the injection site may make the injection easier and more pleasant.
- 2** While firmly holding the MYCLIC® pre-filled pen in position, press the green activation button with your thumb to trigger the injection. You will hear a clicking noise when you press the button. This click signals the start of the injection. **Continue to keep the MYCLIC® pre-filled pen firmly pressed against your skin until you hear a second click,** or wait 10 seconds after the first click (depending on which event occurs first). The injection is triggered regardless of whether the activation button is held down or immediately released.

If you cannot trigger the injection as described, press the pen against your skin more firmly and then press the green activation button again.

## STEP 3 Continued

# 3

- 3 The injection is complete as soon as you hear a second click (or after 10 seconds have passed if you do not hear a second click).
- 4 You can now remove the MYCLIC® pre-filled pen from your skin. The purple needle guard will appear automatically and enclose the needle when you raise the MYCLIC® pre-filled pen.
- 5 **The inspection window of MYCLIC® pre-filled pen should now be completely purple.** This confirms that the dose has been injected correctly.

If slight bleeding occurs at the injection site, press a cotton ball or gauze onto the injection site for 10 seconds. Do not rub the injection site.

**Contact your doctor, pharmacist or nurse if the inspection window has not turned completely purple as this may mean that the pre-filled pen has not injected all of the Enbrel® solution.**

Do not ever try to use the pre-filled pen again and also do not try to use another pre-filled pen without first obtaining permission from your doctor, pharmacist or nurse!



The inspection window has turned purple.  
Purple needle guard appears and covers needle.

## STEP 4 Disposing of the materials

4



(not actual size)

**The MYCLIC® pre-filled pen is intended for single use only.** Dispose of the used pre-filled pen as instructed by your doctor, pharmacist or nurse. Do not attempt to recap the pen.

Ask your doctor, pharmacist or nurse about Enbrel® disposal boxes.



## TRANSPORT AND STORAGE OF ENBREL®



**Do not forget: store the Enbrel® MYCLIC® pre-filled pen in the refrigerator at between 2 and 8 °C (do not freeze) and store in the original packaging to protect the contents from light.**

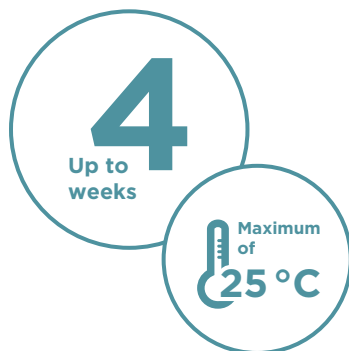
**Please contact your doctor, pharmacist or nurse if you have any further questions.**

If you are flying, please ask your airline in advance whether Enbrel® can be taken on board in your carry-on baggage and whether it can be refrigerated during the flight. Furthermore, please make sure that Enbrel® can be stored under refrigeration at your destination (2-8 °C).

Take Enbrel® as carry-on baggage in the original packaging in the Pfizer cooler bag with cooling elements. Please note that the cooler bag provided by Pfizer is only meant for short-term use.

It is recommended to carry the **Enbrel® prescription** with you, as well as a **letter from your doctor** (in English and German), or the document **«Certificate for transport of Enbrel® (etanercept)»** – if you need to explain to Customs and Airport Security why you have to keep Enbrel® MYCLIC® pre-filled pens in your carry-on baggage. Please do not forget to keep a copy of the prescription and the letter at home in case you lose the originals.

Enbrel® can be stored at room temperature (**up to a maximum of 25 °C**) for a single time period of up to **4 weeks**. Enbrel® must not be refrigerated again once it has been stored at room temperature. Enbrel® that has not been used within 4 weeks after removal from the refrigerator must be discarded.





(not actual size)

## Enbrel® MYCLIC® pre-filled pen 50 mg solution for injection



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