

INSTRUCTIONS FOR USE

Enbrel[®] pre-filled syringe



(not actual size)

Enbrel
Etanerceptum

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PREFACE

Dear Patient,

Your doctor has already given you information on the technical use of Enbrel® pre-filled syringes. We also recommend you read the package leaflet and these instructions carefully before first use. 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 Enbrel® pre-filled syringe

- 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 Enbrel® pre-filled syringes 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 Enbrel® pre-filled syringes 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 syringe.

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.

Never mix Enbrel® with any other medicine in the same syringe.

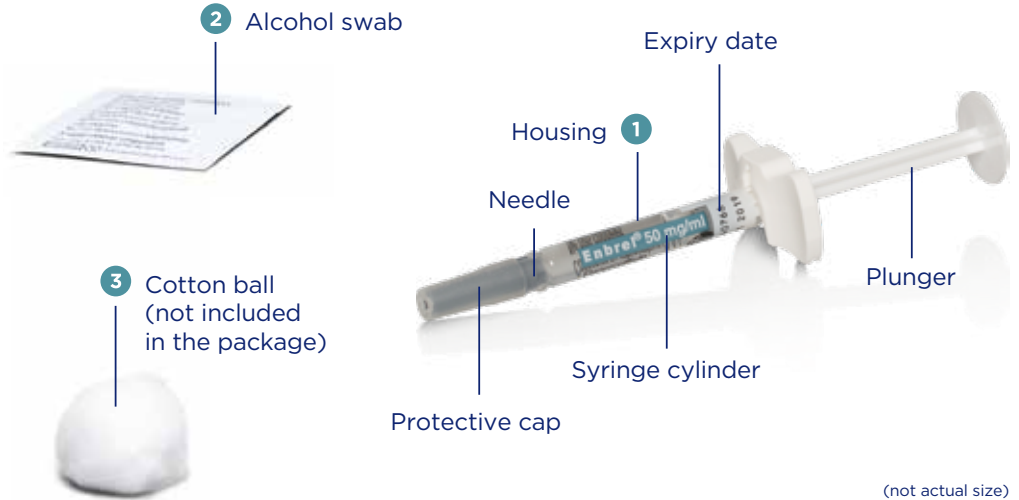
Dispose of the Enbrel® pre-filled syringe as instructed by your doctor, pharmacist or nurse.

Before you inject Enbrel® with the Enbrel® pre-filled syringe

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

Please ensure that **the Enbrel® pre-filled syringe is kept out of the reach of children**.

HOW TO USE THE ENBREL® PRE-FILLED SYRINGE



(not actual size)

The instructions below explain how to use the pre-filled syringe 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 pre-filled syringe 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

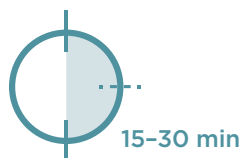
1

Take the Enbrel® package with the pre-filled syringes out of the refrigerator. Remove a pre-filled syringe from the package and place it on a flat work surface. **Do not shake the pre-filled syringe.** Put the package with the second pre-filled syringe or the remaining pre-filled syringes back into the refrigerator.

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

Wait for about 15 to 30 minutes until the pre-filled syringe has reached room temperature. **Do NOT remove the needle protection cap during this time!** **Do NOT warm the pre-filled syringe in any other way** (e.g. in the microwave or in hot water).

Select a clean, well lit and flat work surface.



Wait for about 15 to 30 minutes until the pre-filled syringe has reached room temperature



(not actual size)



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

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

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.

Make sure that the solution in the pre-filled syringe 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.

STEP 2 Selecting the injection site



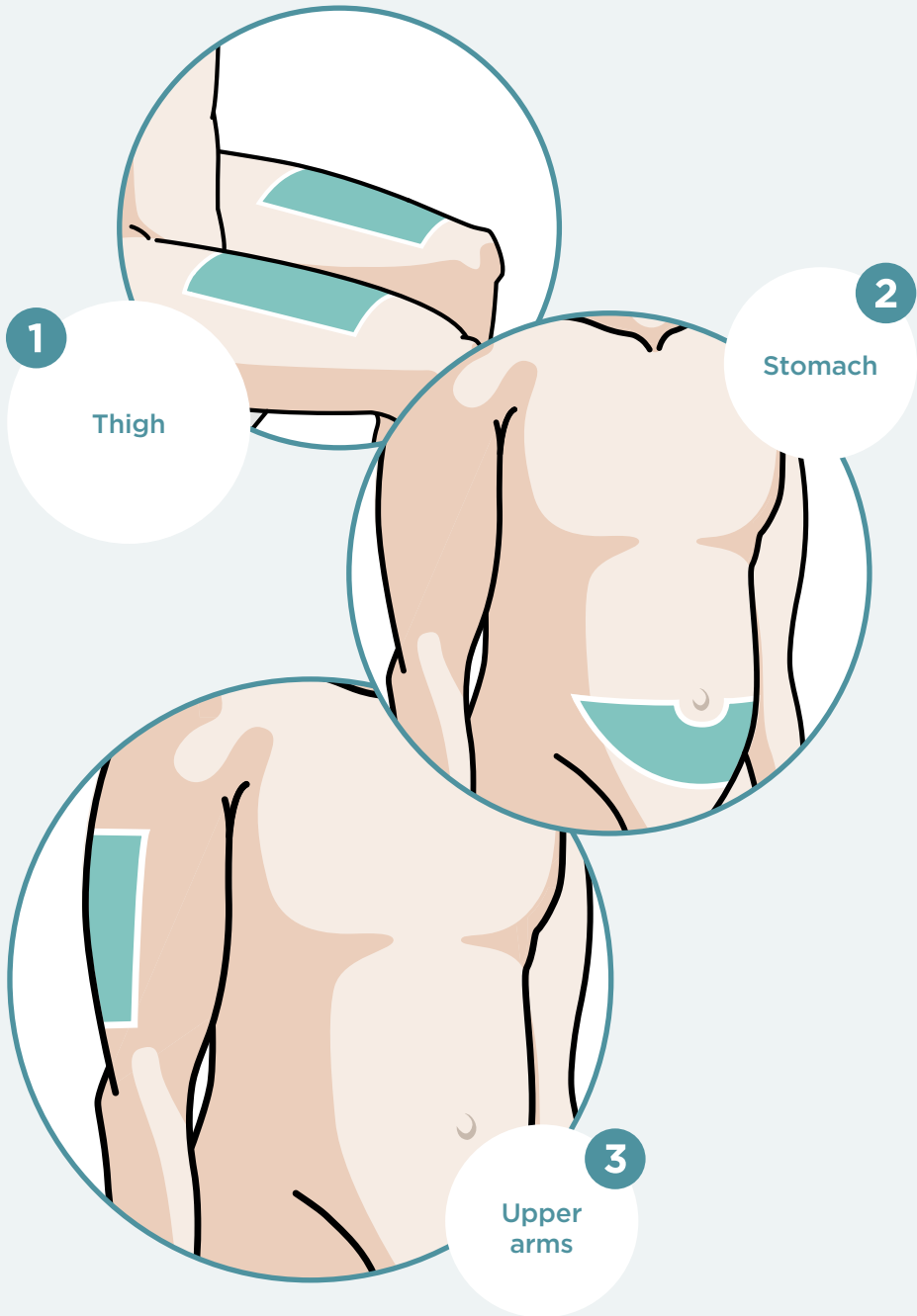
3 areas of the body are specified as **injection sites** for the administration of Enbrel® with the pre-filled syringe:

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

- 1 front area of the thigh
- 2 stomach, except for the area within a radius of 5 cm in the vicinity of the navel
- 3 back of the upper arm

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 pre-filled syringe to reach room temperature.

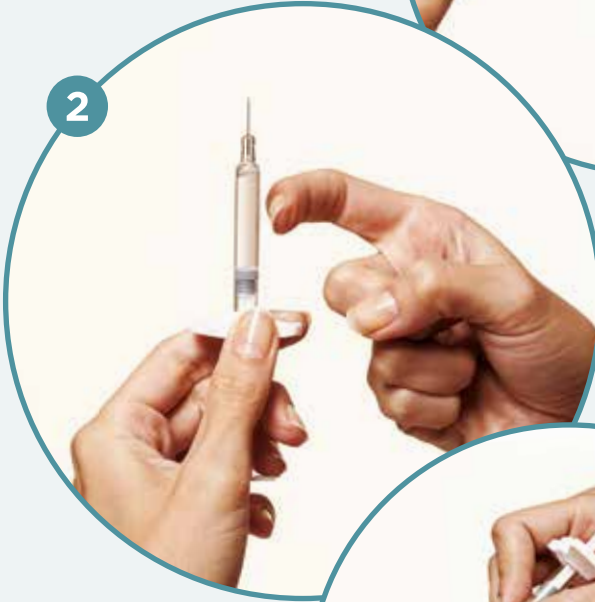
Clean the injection site with the alcohol swab using circular movements and allow it to dry. Do not touch the injection site again.

- 1** As soon as the skin is dry, pick up the pre-filled syringe, hold it by its syringe cylinder and pull off the needle protection cap. There may be a drop of liquid on the tip of needle after the protective cap is removed. The **needle must not come in contact with anything**. Do not touch or push the syringe plunger; this could cause leakage of the injection solution.
- 2** Hold the syringe with the needle pointing upwards and check for the presence of air bubbles. If air bubbles are present, gently tap the syringe with your fingers until the air bubbles have risen to the upper surface of the syringe. Push the plunger slowly upwards to **remove the air bubbles from the syringe**.
- 3** Hold the syringe in one hand like a pencil and press the cleaned skin together carefully with the other hand, holding it tightly. Hold the syringe at about a **45° angle to the skin** and insert the needle into the skin in a quick, short motion. Let go of the skin fold after you have inserted the needle.

1



2



3



45°



STEP 3 Continued

3

4 Pull the syringe plunger back slightly.

Do not inject Enbrel® if blood appears in the syringe, as this means the needle has entered a blood vessel. Pull the needle out and discard the syringe. Repeat the process for preparing an injection with a new Enbrel® pre-filled syringe. Do not use the same pre-filled syringe.

If no blood appears in the syringe, slowly press the plunger all the way down in order to inject the medication.

5 When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as when it was inserted.

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.

STEP 4 Disposing of the materials

4



(not actual size)

The pre-filled syringe is intended for single use only.
Dispose of the used pre-filled syringe as instructed by your doctor, pharmacist or nurse.

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



TRANSPORT AND STORAGE OF ENBREL®



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

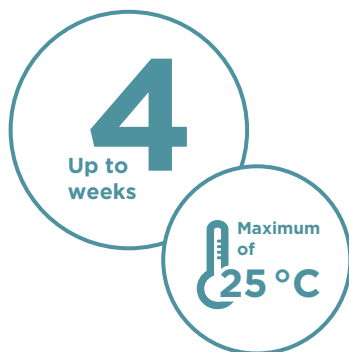
Please contact your doctor, pharmacist or nurse if you have any further questions.

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® pre-filled syringes 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® pre-filled syringe 25 mg and 50 mg solution for injection



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