

**Instructions for Use
Enbrel® (en-brel)
(etanercept)
injection, for subcutaneous use
Single-dose Prefilled Syringe**

How do I prepare and give an injection with Enbrel Single-dose Prefilled Syringe?

There are 2 types of Enbrel single-dose prefilled syringes:

- The 50 mg/mL single-dose prefilled syringe that contains one 50 mg dose of Enbrel.
- The 25 mg/0.5 mL single-dose prefilled syringe that contains one 25 mg dose of Enbrel.

Your healthcare provider will tell you which one to use.

A 50 mg dose can be given as one injection using a 50 mg/mL single-dose prefilled syringe or as two injections using 25 mg/0.5 mL single-dose prefilled syringes. Your healthcare provider will tell you whether the two injections with 25 mg/0.5 mL single-dose prefilled syringes should be given on the same day once a week or on two different days (3 or 4 days apart) in the same week.

Children must weigh at least 138 pounds to use the Enbrel 50 mg/mL single-dose prefilled syringe. Children who weigh less than 138 pounds should use a different form of Enbrel. The Enbrel 25 mg/0.5 mL single-dose prefilled syringe should not be used in pediatric patients weighing less than 68 pounds.

Important: The needle cover on the single-dose prefilled syringe is composed of dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

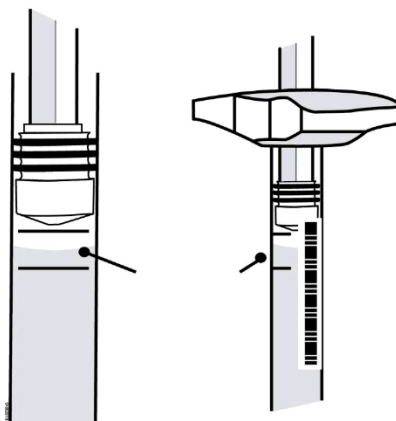
Storage of your Enbrel prefilled syringe

- Store the Enbrel prefilled syringe in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store the Enbrel prefilled syringe in the original carton to protect from light or physical damage.
- If needed, you may store your Enbrel prefilled syringe at room temperature between 68°F to 77°F (20°C to 25°C) for up to 14 days.
 - Once the Enbrel prefilled syringe has reached room temperature, do not put it back in the refrigerator.
- Throw away any Enbrel prefilled syringe that has been stored at room temperature after 14 days.
- **Do not** store the Enbrel prefilled syringe in extreme heat or cold. For example, avoid storing Enbrel prefilled syringe in your vehicle's glove box or trunk.
- **Do not freeze.**
- **Do not shake.**
- **Keep the Enbrel prefilled syringe and all medicines out of the reach of children.**

If you have any questions about storage, contact your healthcare provider or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

Step 1: Setting Up for an Injection

1. Select a clean, well-lit, flat work surface, such as a table.
2. Take the Enbrel carton containing the prefilled syringes out of the refrigerator and place it on your flat work surface. Remove one prefilled syringe and place it on your work surface. Carefully lift the prefilled syringe straight up out of the box. **Do not shake** the prefilled syringe of Enbrel. Place the carton containing any remaining prefilled syringes back into the refrigerator at 36°F to 46°F (2°C to 8°C).
3. Check the expiration date on the prefilled syringe. If the expiration date has passed, **do not** use the prefilled syringe and contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.
4. **Do not** use the prefilled syringe if the needle cover is missing or not securely attached. Call 1-888-4ENBREL (1-888-436-2735).
5. For a more comfortable injection, leave the prefilled syringe at room temperature for about 15 to 30 minutes before injecting. **Do not** remove the needle cover while allowing it to reach room temperature. **Do not** warm Enbrel in any other way (for example, **do not** warm it in a microwave or in hot water).
6. Hold the prefilled syringe with the covered needle pointing down. If bubbles are seen in the syringe, very gently tap the prefilled syringe to allow any bubbles to rise to the top of the syringe. Turn the syringe so that the purple horizontal lines on the barrel are directly facing you. Check to see if the amount of liquid in the syringe falls between the purple lines. The top of the liquid may be curved. If the syringe does not have the right amount of liquid, **do not** use that syringe. Contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.

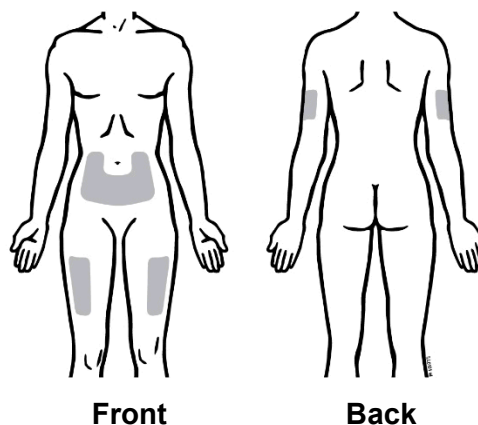


Fill Level Indicator

7. Assemble the additional supplies you will need for your injection. These include an alcohol swab, a cotton ball or gauze, and a sharps disposal container (see “**Step 4: Disposing of Supplies**”).
8. Wash your hands with soap and warm water.
9. Make sure the solution in the prefilled syringe is clear and colorless. You may notice small white particles in the solution. These particles are formed from Enbrel and this is acceptable. However, **do not inject the solution if it is cloudy or discolored, or contains large or colored particles**, call 1-888-4ENBREL (1-888-436-2735).

Step 2: Choosing and Preparing an Injection Site

1. Recommended injection sites for Enbrel using a prefilled syringe include:
 - the front of the middle thigh
 - the stomach area (abdomen), except for the 2-inch area right around the navel (belly button)
 - the outer area of the upper arm (only if someone else is giving you the injection)

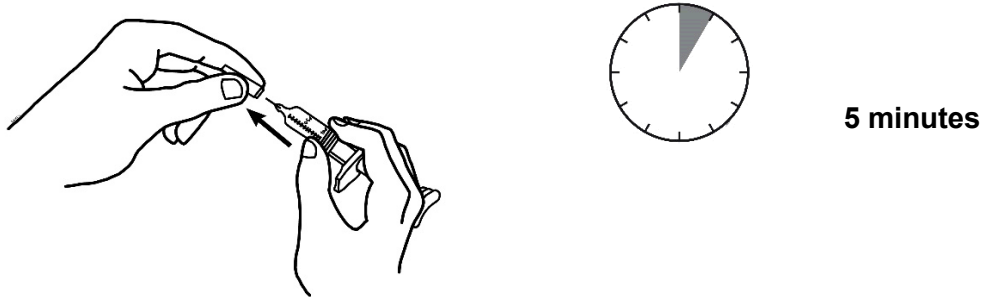


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area of skin where Enbrel is to be injected, wipe the injection site with an alcohol swab. **Do not touch this area again before giving the injection.**

Step 3: Injecting Enbrel Using a Prefilled Syringe

Do not remove the needle cover from the prefilled syringe until you are ready to inject.

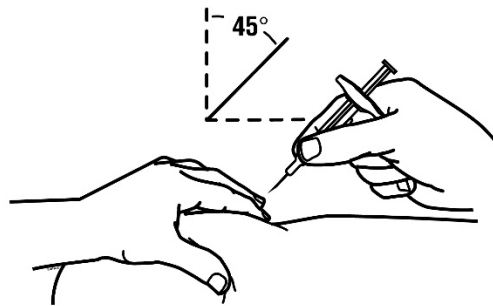
1. Pick up the prefilled syringe from your flat work surface. Hold the barrel of the prefilled syringe with one hand and pull the needle cover straight off, only when you are ready to inject. **Do not** leave the needle cover off for more than **five minutes**. This can dry out the medicine.



To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it, and **do not** try to put the needle cover back onto the prefilled syringe.

When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. **Do not** touch the needle or allow it to touch any surface. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out.

2. Holding the syringe with the needle pointing up, check the syringe for air bubbles. If there are bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.
3. Holding the syringe in one hand like a pencil, use the other hand to gently pinch a fold of skin at the cleaned injection site and hold it firmly.
4. With a quick and “dart-like” motion, insert the needle at a 45-degree angle into the skin.



5. When the needle is completely inserted into the skin, let go of 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 Enbrel solution at a slow, steady rate.

6. 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.

Step 4: Disposing of Supplies

The syringe should **never** be reused. **Never** recap a needle.

- Put the used prefilled syringes in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) prefilled syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used syringes and needles. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **Do not** reuse the syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

A healthcare provider familiar with Enbrel should answer all questions. Call 1-888-4ENBREL (1-888-436-2735) or visit www.enbrel.com for more information about Enbrel.

This Instructions for Use have been approved by the U.S. Food and Drug Administration.

AMGEN[®]

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