

Instructions for Use
Enbrel® (en-brel)
(etanercept)
injection, for subcutaneous use
Single-Dose Prefilled SureClick® Autoinjector
50 mg/mL

This Instructions for Use contains information on how to inject ENBREL.

Guide to parts

Before use	After use
<p>Purple start button</p> <p>Expiration date</p> <p>Window</p> <p>Medicine</p> <p>White cap on</p> <p style="text-align: right;">Green safety guard (needle inside)</p>	<p>Expiration date</p> <p>Yellow window (injection complete)</p> <p>Green safety guard (needle inside)</p> <p>White cap off</p>
<p>Important: Needle is inside the green safety guard.</p>	

Important

Important Information You Need to Know Before Injecting ENBREL:

- It is important that you **do not** try to give yourself or someone else the injection unless you have received training from your healthcare provider.
- The white cap on the Enbrel SureClick autoinjector contains a needle cover (located inside the cap) that contains dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

Storing your Enbrel SureClick autoinjector:

- Keep the autoinjector and all medicines out of the reach of children.
- Keep the autoinjector in the original carton to protect from light.
- Keep the autoinjector in the refrigerator at 36°F to 46°F (2°C to 8°C).
- After removing from the refrigerator, the autoinjector may be kept at room temperature between 68°F to 77°F (20°C to 25°C) and must be used within 30 days. **Do not** put it back in the refrigerator after it has reached room temperature.
- Throw away Enbrel that has been stored at room temperature for more than 30 days.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing the autoinjector in your vehicle's glove box or trunk.
- **Do not** freeze or use the autoinjector if it has been frozen.

Using your Enbrel SureClick autoinjector:

- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject. Leaving the cap off for more than 5 minutes can dry out the medicine.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector and call 1-888-4ENBREL (1-888-436-2735).
- **Children must weigh at least 138 pounds to use the Enbrel SureClick autoinjector. Children who weigh less than 138 pounds should use a different form of Enbrel.**

For more information or help, contact your healthcare provider, visit www.enbrel.com or call 1-888-4ENBREL (1-888-436-2735).

Step 1: Preparing to inject ENBREL

1A Remove the autoinjector from the carton.

Carefully lift the autoinjector straight up out of the carton.

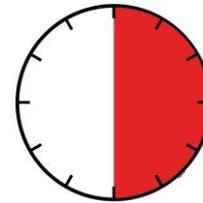
Before you inject, always check the label of the autoinjector to make sure you have the correct medicine and the correct dose of ENBREL.

Put the original carton with any unused autoinjectors back in the refrigerator.

Wait at least **30 minutes** for the autoinjector to reach room temperature before injecting.

This is important for administering the entire dose and helps minimize discomfort. ENBREL may take longer to inject if it has not reached room temperature. **Do not** heat the autoinjector. Let it come to room temperature naturally.

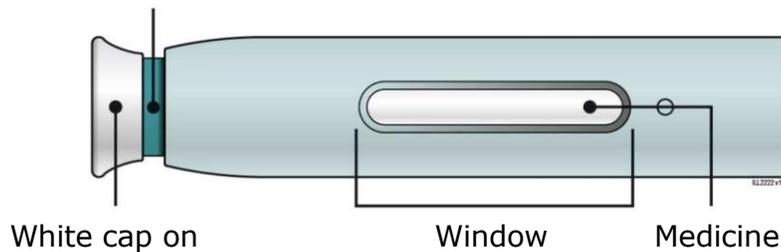
30 minutes



- **Do not** put the autoinjector back in the refrigerator after it has reached room temperature.
- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave.
- **Do not** leave the autoinjector in direct sunlight.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector yet.

1B Inspect the Enbrel SureClick autoinjector.

Green safety guard (needle inside)



Make sure the medicine in the window is clear and colorless.

It is okay if you see small white particles in the medicine.

- **Do not** use the autoinjector if the medicine is cloudy or discolored or contains large lumps, flakes, or colored particles.
- **Do not** use the autoinjector if any part appears cracked or broken.
- **Do not** use the autoinjector if the autoinjector has been dropped.
- **Do not** use the autoinjector if the white cap is missing or not securely attached.
- **Do not** use the autoinjector if the expiration date printed on the label has passed.

In all cases, use a new autoinjector and call 1-888-4ENBREL (1-888-436-2735).

1C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- New autoinjector
- Alcohol wipes
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps disposal container (**see Step 4: Finish**)



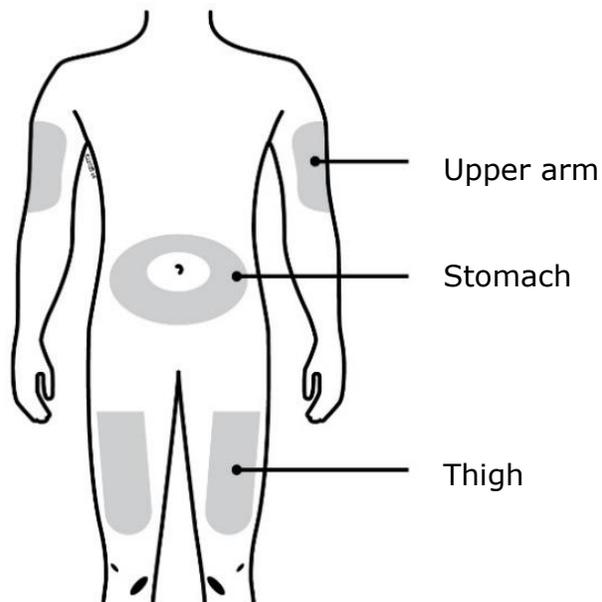
1D Prepare and clean your injection site.

Only use these injection sites:

- Thigh
- Stomach (abdomen), except for a **2** inch area around your navel (belly button)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean your injection site with an alcohol wipe. Let your skin dry.

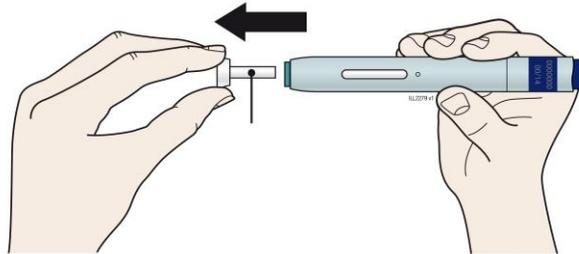
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot you used for the last injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- Avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.



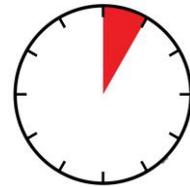
Step 2: Get ready

2A Pull the white cap straight off only when you are ready to inject.

Do not leave the white cap off for more than **5 minutes**. This can dry out the medicine.



5 minutes



White cap

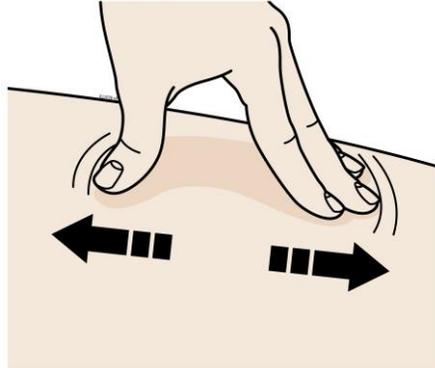
It is normal to see a drop of liquid at the end of the needle or green safety guard.

- **Do not** twist, bend, or wiggle the white cap.
- **Do not** put the white cap back onto the autoinjector.
- **Do not** put fingers into the green safety guard.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.

If you are unable to inject, please contact your healthcare provider.

2B Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.

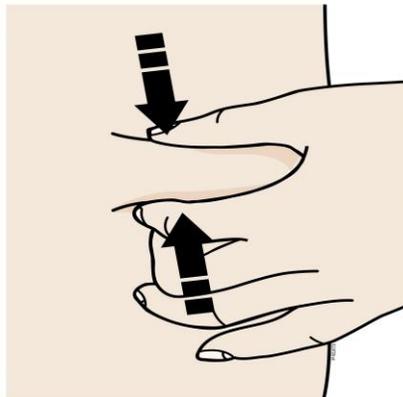
Stretch method:



Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **2** inches wide.

OR

Pinch method:

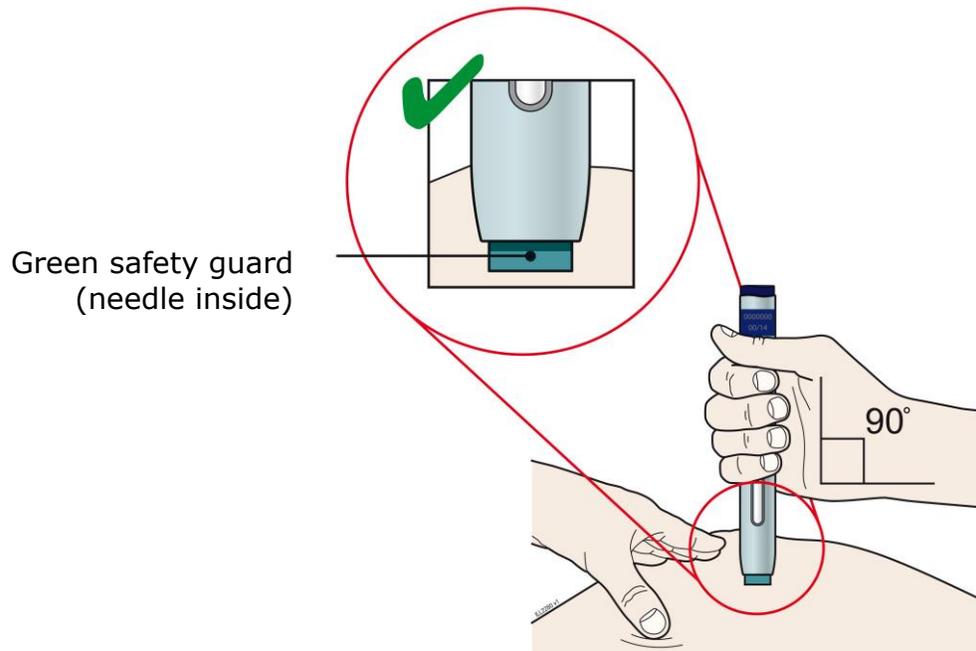


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

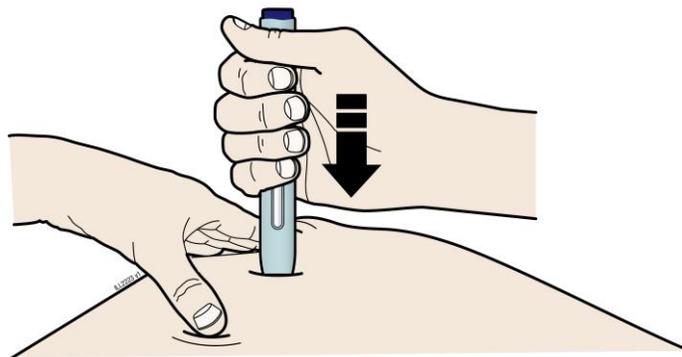
Important: Keep skin stretched or pinched while injecting.

Step 3: Inject

3A Keep holding the stretched or pinched skin. With the white cap off, **put** the green safety guard on your skin at 90 degrees. **The needle is inside** the green safety guard. Do not touch the purple start button yet.

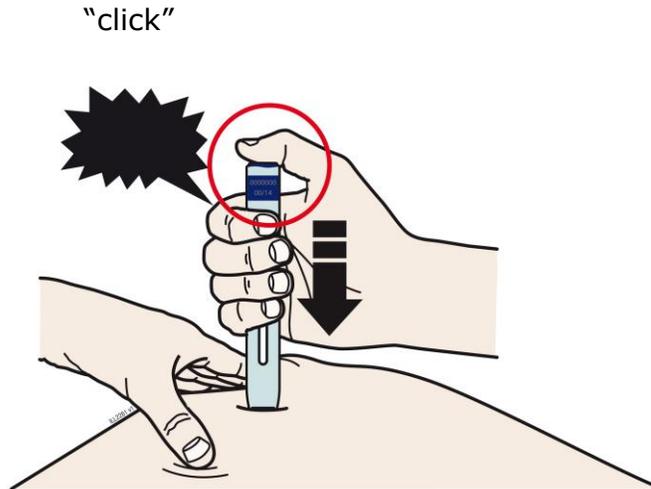


3B Firmly **push** down the autoinjector onto the skin until it stops moving.

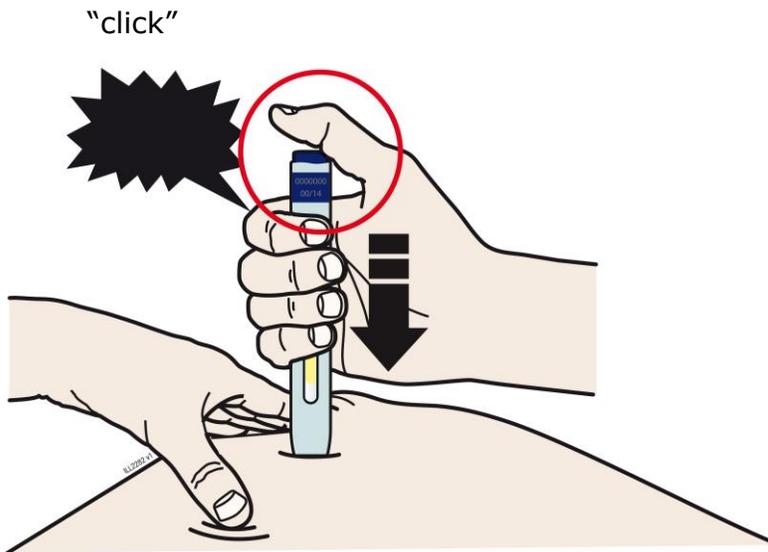


Important: You must push all the way down but **do not** touch the purple start button until you are ready to inject.

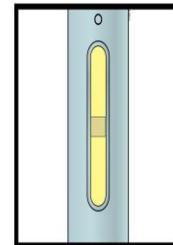
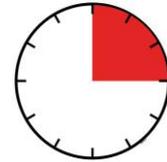
3C When you are ready to inject, **press** the purple start button. You will hear a click.



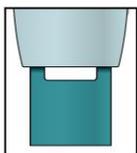
3D Keep **pushing** the autoinjector down on your skin. Then lift your thumb while still holding the autoinjector on your skin. Your injection could take about 15 seconds to complete.



15 seconds



Window turns from clear to yellow when the injection is done. You may hear a second click.



NOTE: After you remove the autoinjector from your skin, the needle will be automatically covered.

Important: When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.

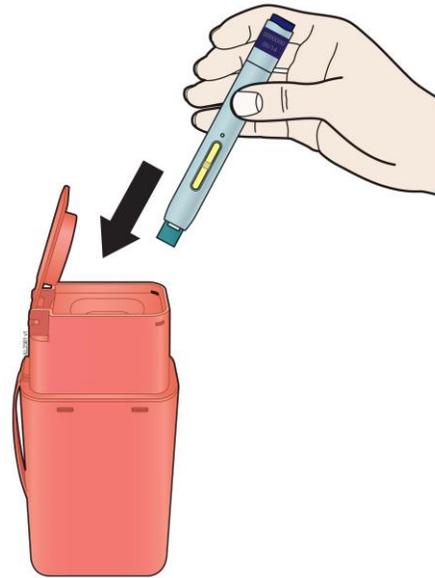
Step 4: Finish

4A Throw away the used autoinjector and white needle cap.

Put the used autoinjector and white needle cap in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the autoinjector or white cap in your household trash.

If you do not have an 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 needles and syringes. 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 dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

- **Do not** reuse the autoinjector.
- **Do not** recap the autoinjector or put fingers into the green safety guard.

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

4B Check the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site.
Apply an adhesive bandage if needed.

Do not rub the injection site.

Commonly Asked Questions

What will happen if I press the purple start button before I am ready to do the injection on my skin?

Even when you press the purple start button, the injection will only happen when the green safety guard is also pushed into the autoinjector.

Can I move the autoinjector around on my skin while I am choosing an injection site?

It is okay to move the autoinjector around on the injection site as long as you **do not** press the purple start button. However, if you press the purple start button and the green safety guard is pushed into the autoinjector, the injection will begin.

Can I release the purple start button after I start my injection?

You can release the purple start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the purple start button pop up after I release my thumb?

The purple start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What do I do if I did not hear a second click?

If you did not hear a second click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the autoinjector or my injection?

A healthcare provider familiar with ENBREL should be able to answer your questions. For more information, call 1-888-4ENBREL (1-888-436-2735) or visit www.enbrel.com.

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



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