

Instructions for Use

Welcome!

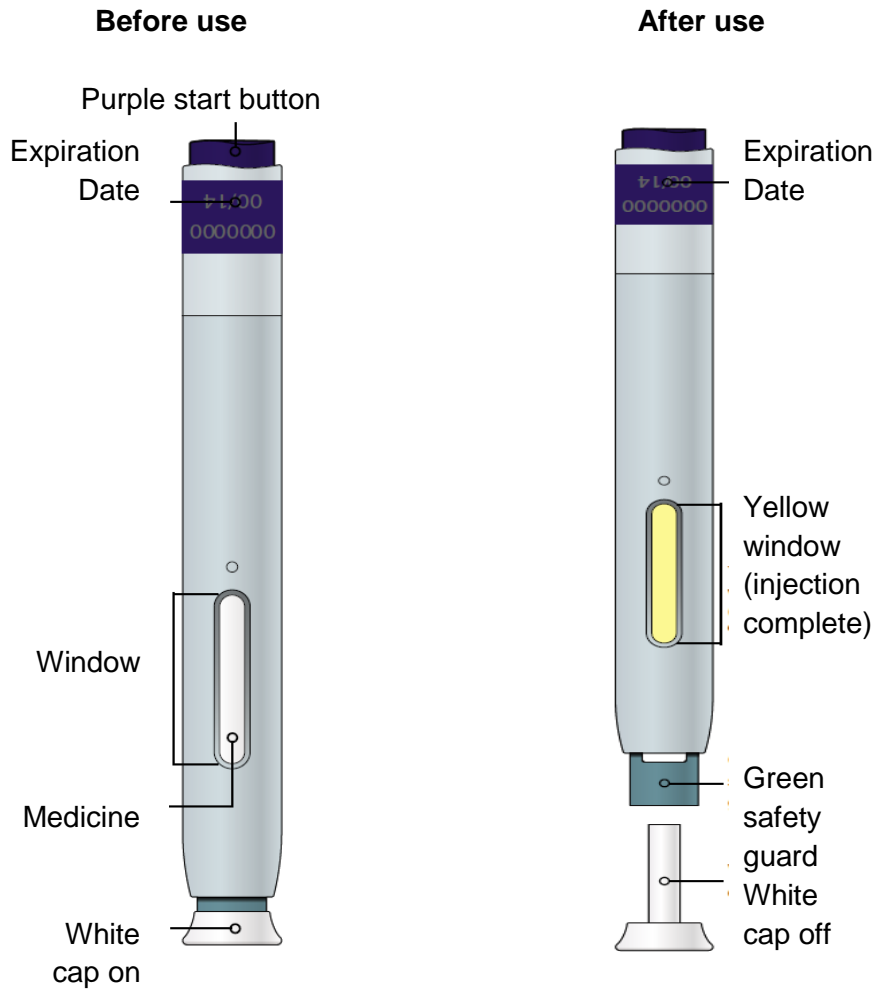
The Enbrel SureClick autoinjector is a single-dose prefilled autoinjector. It contains one 50 mg dose of Enbrel.

Your healthcare provider has prescribed Enbrel SureClick autoinjector for your injections. If your healthcare provider decides that you or a caregiver may be able to give your injections of Enbrel at home, you should receive training on the right way to prepare and inject Enbrel. Do not try to inject yourself until you have been shown the right way to give the injections by your healthcare provider.

Please read all of the instructions before using Enbrel SureClick autoinjector. Call your healthcare provider if you or your caregiver has any questions about the right way to inject Enbrel.

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

Guide to parts



Important: Needle is inside

Important

Before you use an Enbrel SureClick autoinjector, read this important information:

Storing your Enbrel SureClick autoinjectors

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

Using your Enbrel SureClick autoinjector

- It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- **Do not** use an Enbrel SureClick autoinjector after the expiration date on the label.
- **Do not** shake the Enbrel SureClick autoinjector.
- **Do not** remove the white cap from the Enbrel SureClick autoinjector until you are ready to inject.
- **Do not** use an Enbrel SureClick autoinjector if it has been dropped on a hard surface. Part of the Enbrel SureClick autoinjector may be broken even if you cannot see the break. Use a new Enbrel SureClick autoinjector, and call 1-888-4ENBREL (1-888-436-2735).
- The white needle cap on the Enbrel SureClick autoinjector contain dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.
- **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.**

If you have any questions about usage, contact your healthcare provider, visit www.enbrel.com or call 1-888-4ENBREL (1-888-436-2735).

Step 1: Prepare

A Remove one Enbrel SureClick autoinjector from the package.

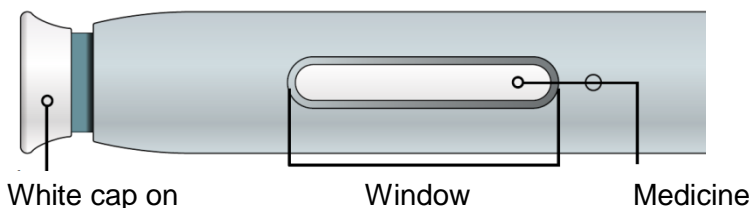
Carefully lift the autoinjector straight up out of the box.

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

Leave the autoinjector at room temperature for at least **30** minutes before injecting.

- **Do not** put the autoinjector back in the refrigerator once 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** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector yet.

B Inspect the Enbrel SureClick autoinjector.



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.
 - Any part appears cracked or broken.
 - The white cap is missing or not securely attached.
 - 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).

C Gather all materials needed for your injection.

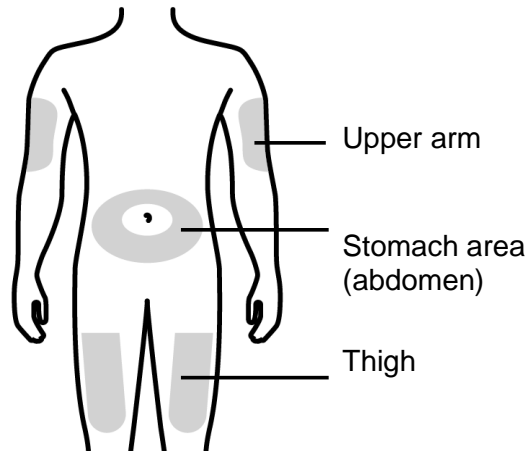
Wash your hands thoroughly with soap and water.

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

- New autoinjector
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container. See “**Step 4: Finish**”



D Prepare and clean your injection site.



You can use:

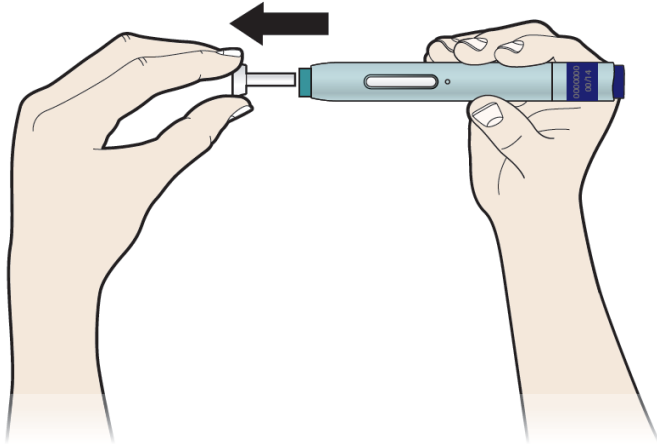
- Your thigh
- Stomach area (abdomen), except for a **2**-inch area right around your navel (belly button)
- Outer area of upper arm (only if someone else is giving you the injection)

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 need to use the same injection site, just make sure it is not the same spot on that site you used last time.
 - **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- If you have psoriasis, you should avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.

Step 2: Get ready

E Pull white cap straight off when you are ready to inject.

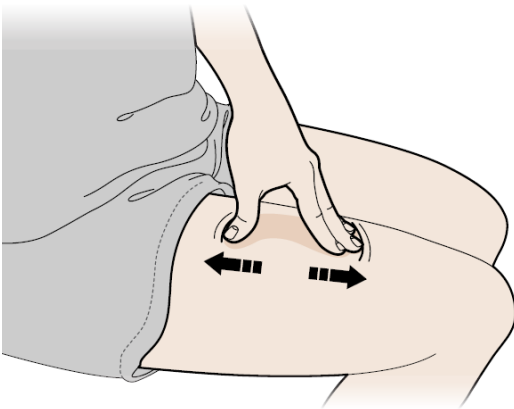


It is normal to see a drop of liquid at the end of the needle or green safety guard.

- **Do not** twist or bend the white cap.
- **Do not** put the white cap back onto the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.

F Stretch or pinch your injection site to create a firm surface.

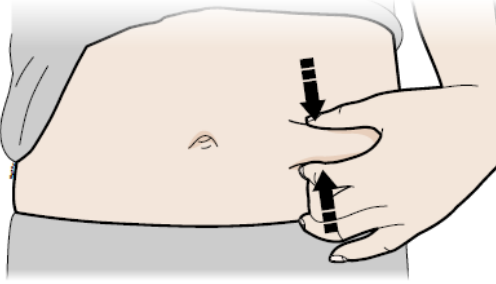
Stretch method



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

OR

Pinch method

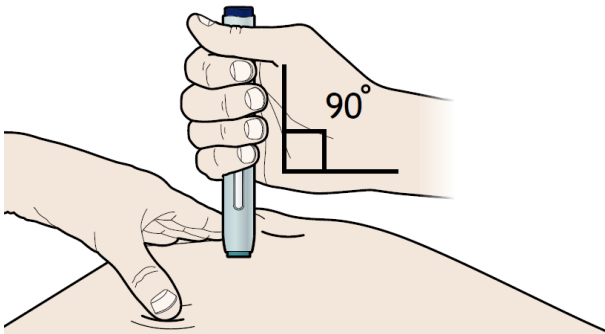


Pinch skin firmly between your thumb and fingers, creating an area about **2** inches wide.

Important: Keep the skin stretched or pinched while injecting.

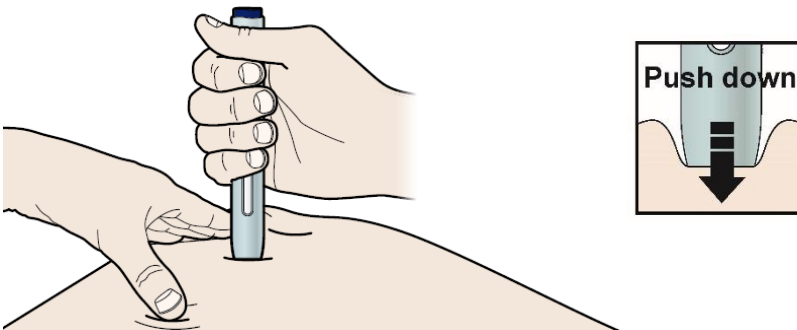
Step 3: Inject

G Hold the stretch or pinch. With the white cap off, **place** the autoinjector on your skin at 90 degrees.



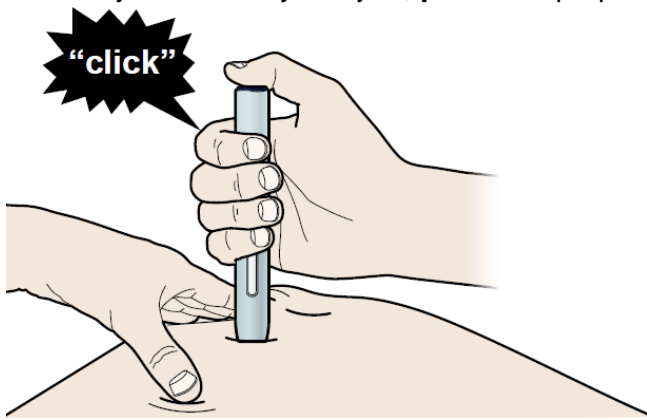
Important: Do not touch the purple start button yet.

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

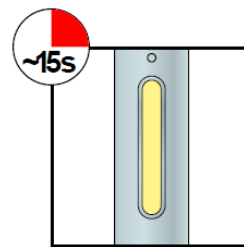
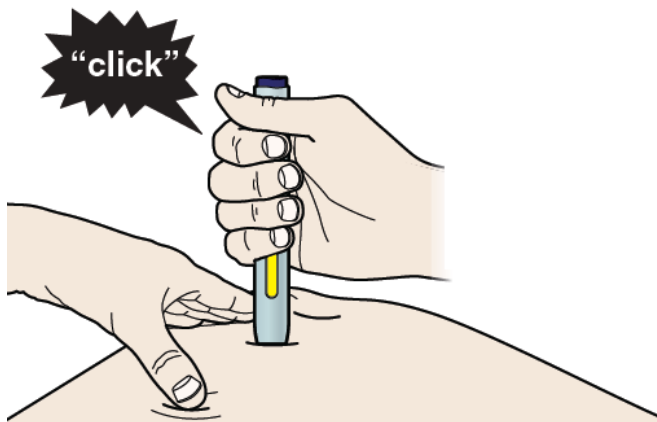


Important: You must push all the way down but do not touch purple start button until you are ready to inject.

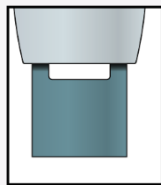
I When you are ready to inject, **press** the purple start button.



J Keep **pushing** down on your skin. Your injection could take about **15** seconds.



Window turns yellow
when injection is done



Note: After you remove 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

K Discard the used autoinjector and the white cap.



- Put the used SureClick autoinjector in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the SureClick autoinjector 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 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** reuse the autoinjector.
- **Do not** recycle the autoinjector or sharps disposal container or throw them into household trash.

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

L Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

Please see the Medication Guide for Enbrel and accompanying Prescribing Information.

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 click after pushing the device down on my skin for 15 seconds?

If you did not hear a 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?

If you have any questions about the autoinjector, its storage, or about your injection, contact your healthcare provider or visit www.enbrel.com or call 1-888-4ENBREL (1-888-436-2735) for help.

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



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