

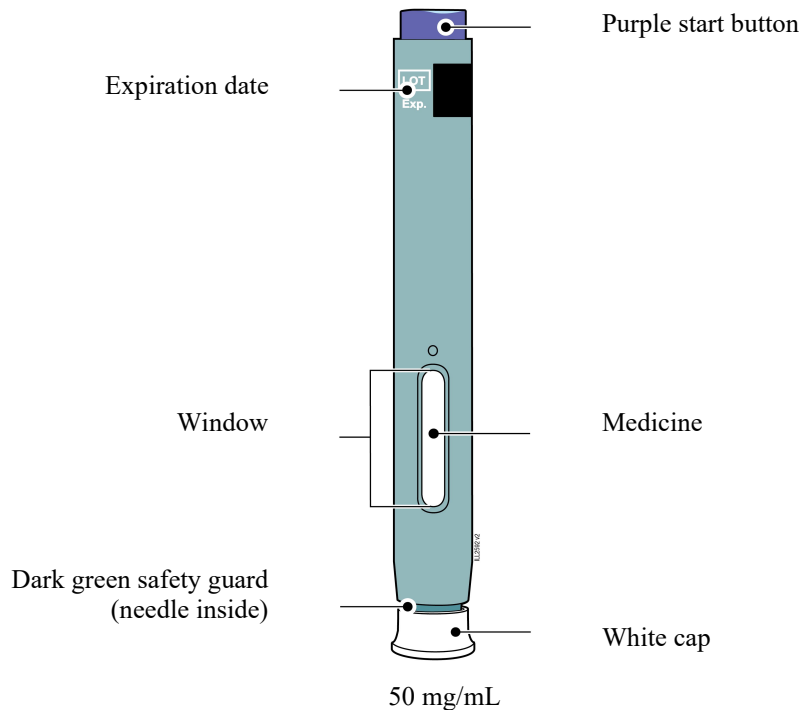
INSTRUCTIONS FOR USE
ENBREL® (en-brel)
(etanercept)
injection, for subcutaneous use
50 mg/mL
single-dose prefilled SureClick® autoinjector

This Instructions for Use contains information on how to inject ENBREL with a SureClick autoinjector.

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 or nurse.

The medicine in the ENBREL autoinjector is for injection under the skin (subcutaneous injection). See the ENBREL Medication Guide for information about ENBREL.

Getting to know your prefilled autoinjector



1. Important Information You Need to Know Before Injecting ENBREL

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **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.
- **Do not** use the autoinjector if it has been frozen.

- **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.**
- The autoinjector is not made with natural rubber latex.

Frequently asked questions:

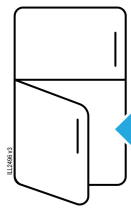
For additional information and answers to frequently asked questions, visit www.enbrel.com.

Where to get help:

If you want more information or help using ENBREL:

- Contact your healthcare provider,
- Visit www.enbrel.com, or
- Call 1-888-4ENBREL (1-888-436-2735).

2. Storing and Preparing to Inject ENBREL



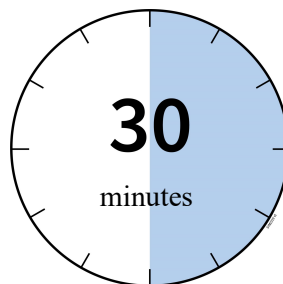
Refrigerate in carton until ready to use

2a Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector and all medicines out of the sight and reach of children.

WAIT



2b Wait 30 minutes for the autoinjector to reach room temperature.

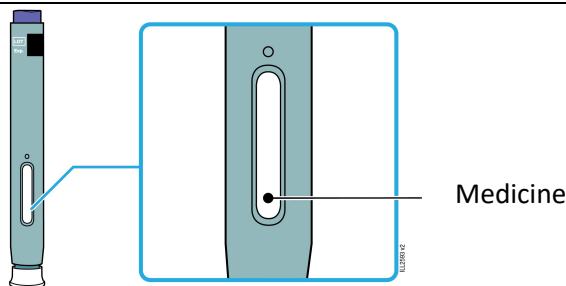
- Remove the number of autoinjectors you need for your injection and put any unused autoinjectors back into the refrigerator.
- Lift the autoinjector(s) straight up out of the box.
- Let the autoinjector warm up naturally.
- **Do not** heat the autoinjector with hot water, a microwave, or direct sunlight.
- **Do not** shake the autoinjector at any time.
- Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.



2c You may keep ENBREL at room temperature for up to 30 days, if needed.

- For example, when you are traveling, you may keep ENBREL at room temperature.
 - Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - **Do not** put it back in the refrigerator.
 - Record the date you removed it from the refrigerator and use it within **30** days.

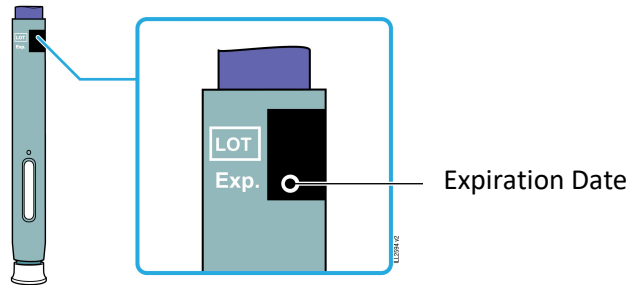
Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within **30** days.



2d Inspect the medicine. It should be clear and colorless to slightly yellow.

- It is okay to see air bubbles or small white particles in the autoinjector.
- **Do not** use ENBREL if the medicine is cloudy, discolored, or contains large lumps, flakes or colored particles.

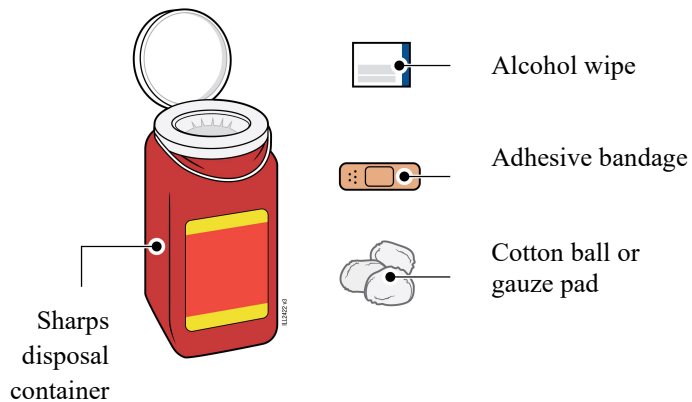
Important: If the medicine is cloudy, discolored, or contains large lumps, flakes or colored particles, or if the autoinjector is damaged or expired, call 1-888-4ENBREL (1-888-436-2735).



2e Check the expiration date (Exp.) and inspect the autoinjector for damage.

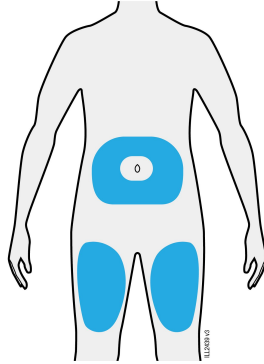
- **Do not** use the autoinjector if the expiration date has passed.
- **Do not** use the autoinjector if:
 - the white cap is missing or loose.
 - it has cracks or broken parts.
 - it has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

3. Getting Ready for Your Injection



3a Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- ENBREL autoinjector (room temperature)
- Sharps disposal container [see Disposing of ENBREL and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad



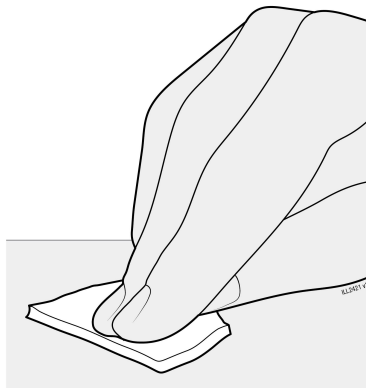
3b Inject into 1 of these sites.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Someone else can inject in your thigh, stomach, or back of the upper arm.
- Choose a different site for each injection.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, hard, raised, thick or scaly skin patch or lesion.



3c Wash hands thoroughly with soap and water.

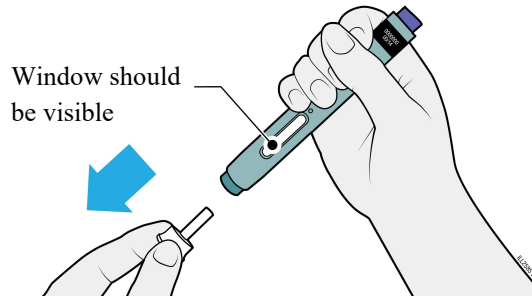


3d Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

4. Injecting ENBREL

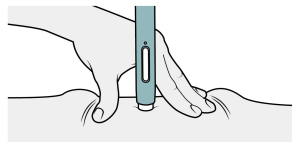
Important: Only remove the white cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



4a Grasp the autoinjector so you can see the window. Pull the white cap straight off. You may need to pull hard.

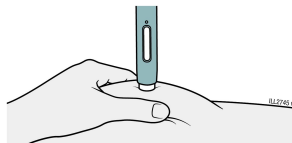
- **Do not** twist, bend or wiggle the white cap to pull it off.
- **Never** put the white cap back on. It may damage the needle.
- **Do not** put your finger inside the dark green safety guard.
- It is normal to see a drop of medicine at the end of the needle or dark green safety guard.

STRETCH



OR

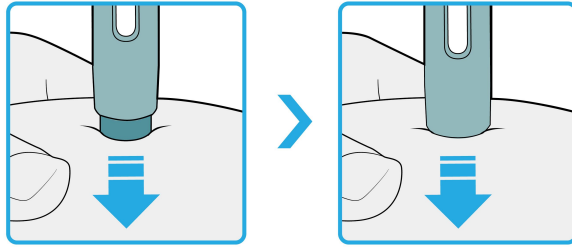
PINCH



4b Stretch or pinch the skin to create a firm surface at the injection site. Place the dark green safety guard straight against the skin.

- Keep the skin **stretched or pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

PUSH
and hold against skin

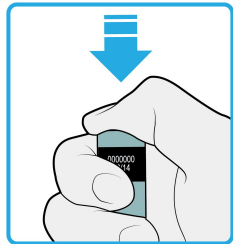


4c

Firmly push the autoinjector down until the dark green safety guard stops moving. Hold the autoinjector down, do not lift.

- The dark green safety guard pushes in and unlocks the purple start button.

PRESS
purple start button

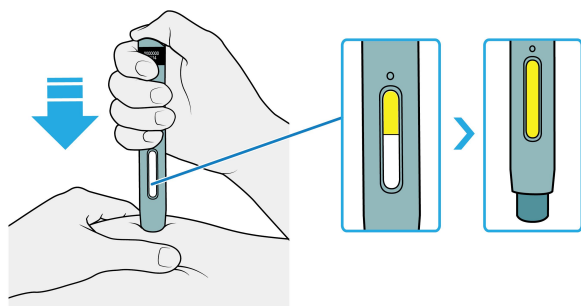


4d

Keep pushing the autoinjector down and press the purple start button to start the injection.

- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the purple start button.

WATCH and CONFIRM
that the window turns fully yellow



4e

Keep pushing the autoinjector down. When the window is fully yellow, the injection is complete.

- The injection may take up to **15** seconds to complete.
- You may hear or feel a click.
- Lift the autoinjector away from your skin.
- The dark green safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your healthcare provider right away.

5. Disposing of ENBREL and Checking the Injection Site

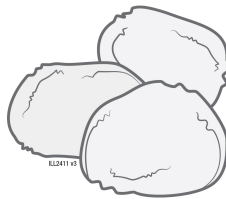
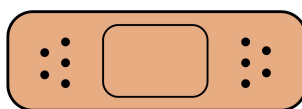


5a

Place the used autoinjector and white cap in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the dark green safety guard.



5b

Check the injection site.

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

Additional information about your sharps disposal container

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.

Disposing of sharps disposal containers:

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.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children. For more information or help call 1-888-4ENBREL (1-888-436-2735).

ENBREL (etanercept)



Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

U.S. License Number 1132

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

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