

INSTRUCTIONS FOR USE

ENBREL® [en-brel]

(etanercept)

injection, for subcutaneous use

50 mg/mL

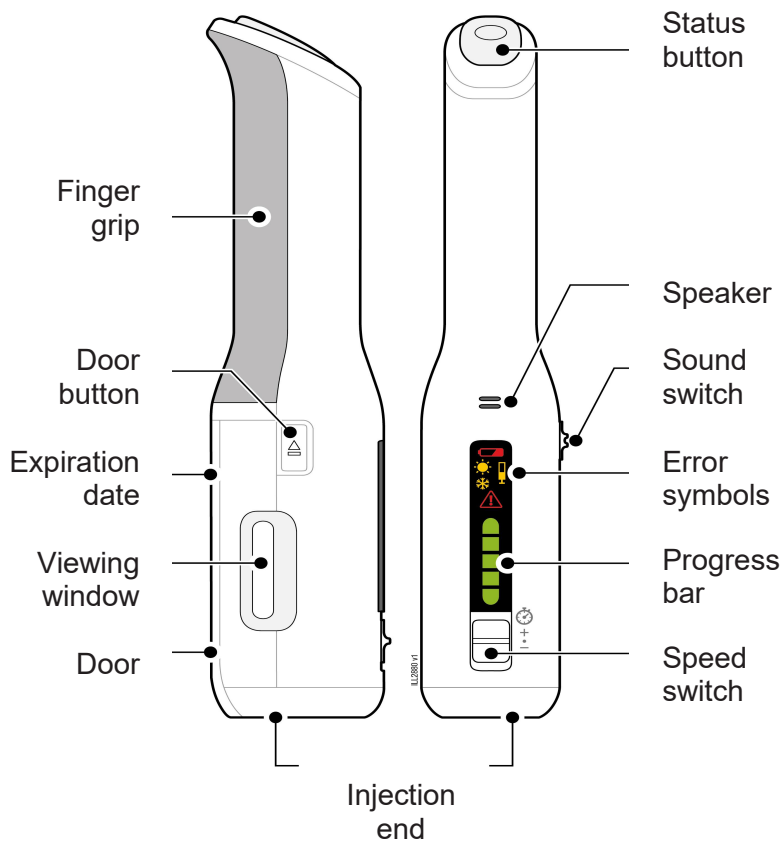
**ENBREL Mini® Single-dose Prefilled Cartridge
for use with all AutoTouch® Reusable Autoinjectors**

This Instructions for Use contains information on how to inject the ENBREL Mini single-dose prefilled cartridge with all AutoTouch reusable autoinjectors.

If your healthcare provider decides that ENBREL injections may be given at home, you or your caregiver should receive training on the right way to prepare and inject ENBREL. Do not try to inject until you or your caregiver have been shown the right way to give the injections by your healthcare provider or nurse.

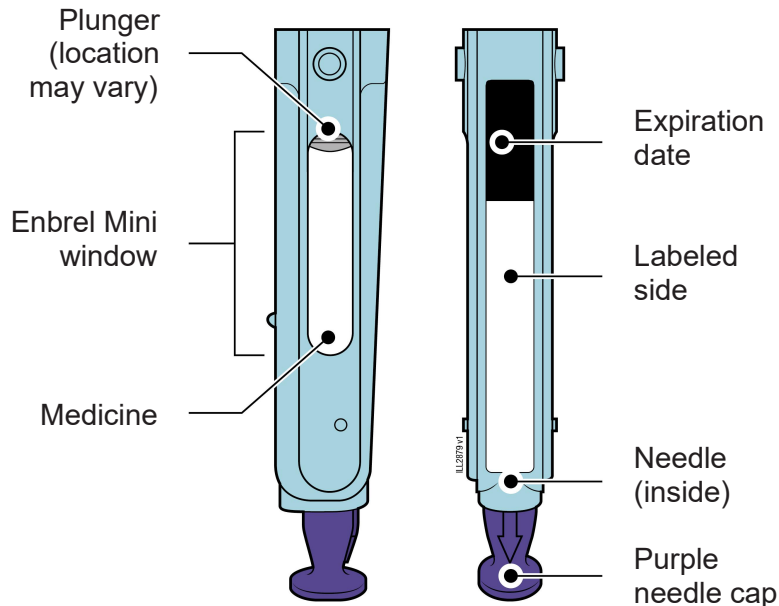
The medicine in the ENBREL Mini single-dose prefilled cartridge is for injection under the skin (subcutaneous injection). See the ENBREL Medication Guide for information about ENBREL.

AutoTouch® Reusable Autoinjector



- i** To learn more about autoinjector features, see the User Manual, section "Guide to Parts."
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Enbrel Mini® Single-dose Prefilled Cartridge



Important: Do not remove the purple needle cap until step 11.

- i** To learn more about cartridge features, see the User Manual, section "Guide to Parts."
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Frequently asked questions

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

Where to get help

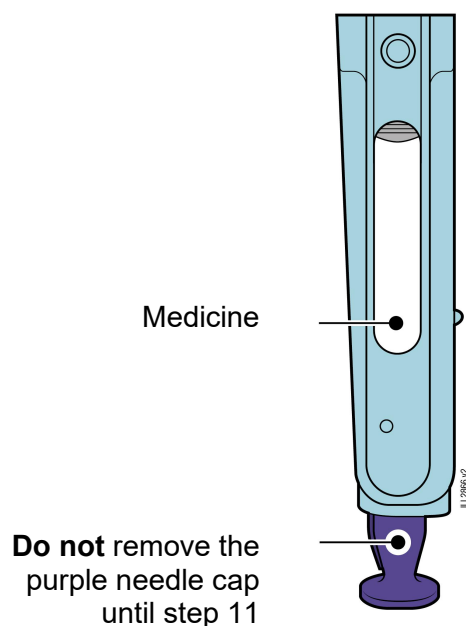
If you want more information or help using ENBREL:

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



1 Wait 30 minutes for the cartridge to reach room temperature.

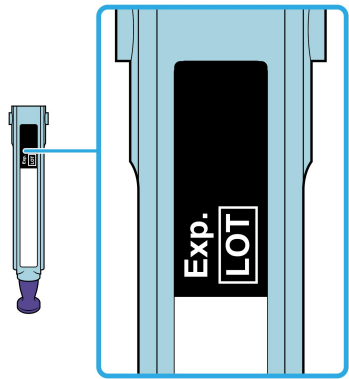
- Remove 1 cartridge from the carton in the refrigerator.
- Put the carton containing any unused cartridges back in the refrigerator.
- Let the cartridge warm up naturally.
- **Do not** heat the cartridge with hot water, a microwave, or direct sunlight.
- **Do not** put the cartridge back in the refrigerator once it reaches room temperature.



2 Inspect the medicine. It should be clear and colorless.

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

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



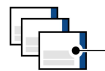
Expiration date

3 Check the expiration date (Exp.) and inspect the cartridge for damage.

- **Do not** use the cartridge if the expiration date has passed.
- **Do not** use the cartridge if:
 - the purple needle cap is missing or loose,
 - it has cracks or broken parts, or
 - it has been dropped on a hard surface.



Sharps disposal container



3 Alcohol wipes



Adhesive Bandage



Cotton balls or gauze pads

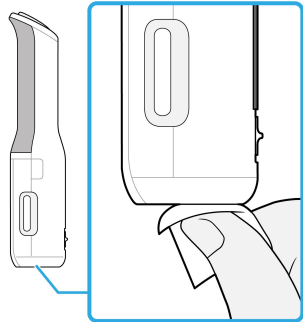
4 Gather and place the following items for the injection on a clean, flat, and well-lit surface:

- AutoTouch reusable autoinjector,
- 1 Enbrel Mini cartridge (room temperature),
- Sharps disposal container [see Completing the Injection],
- 3 Alcohol wipes,
- Adhesive bandage, and
- Cotton balls or gauze pads.



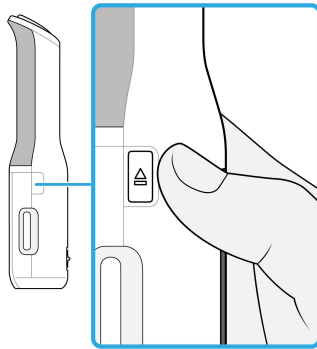
- 5 Wash your hands thoroughly with soap and water.**

Getting Ready to Inject ENBREL

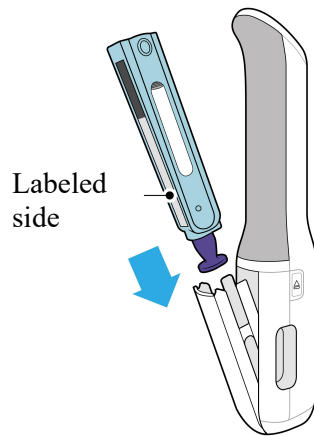


- 6 Clean the injection end of the autoinjector with an alcohol wipe.**

- Let the injection end dry on its own.
- **Do not** touch this area again before injecting.
- **Do not** use the autoinjector if:
 - the expiration date has passed,
 - it has cracks or broken parts, or
 - it has been dropped on a hard surface.



- 7 Press the door button to open the autoinjector door.**
- **Do not** block the door while pushing the door button.

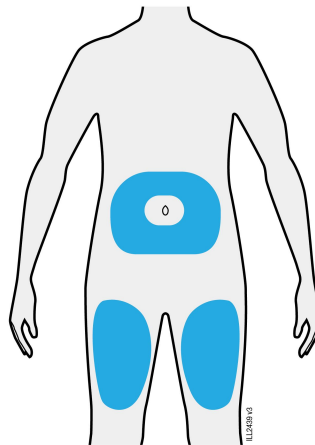


8 Insert the cartridge with the purple needle cap down and the labeled side facing out.

- The cartridge will slide all the way down into the autoinjector.
- **Do not** force the cartridge into the autoinjector door.
- Once the cartridge is inserted, push the door to close it.
- **Do not** remove the purple needle cap until step 11.



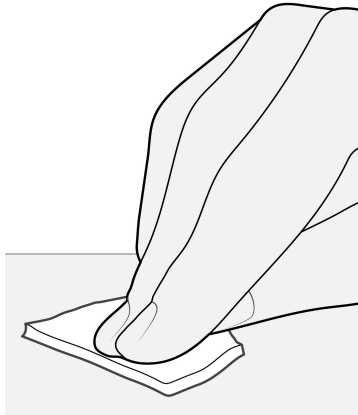
If the status button flashes red, see the User Manual, section "Troubleshooting."



9 Select 1 of these injection site locations.

- You can inject into the:
 - **Stomach** (at least 2 inches away from the belly button), or
 - **Thigh.**
- Another person may give you the injection in the back of your upper arm.
- Choose a different site for each injection.

Important: Avoid areas with scars, stretch marks, where the skin is tender, bruised, red, hard, or areas with psoriasis.

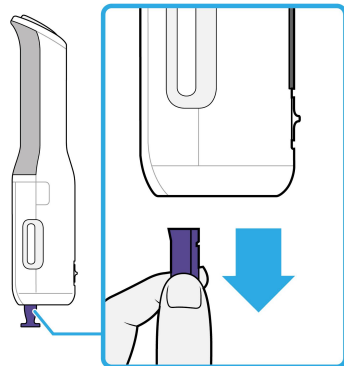


10 Clean the injection site with a new alcohol wipe.

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

Injecting ENBREL

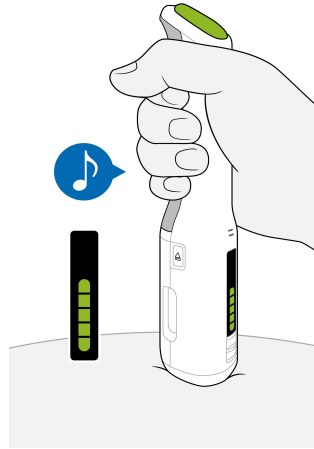
Important: Only remove the purple needle cap when you can inject right away (within 5 minutes) as the medicine can dry out. **Do not** recap.



11 Pull the purple needle cap straight down to remove.

- **Do not** twist or bend the purple needle cap to pull it off.
- **Never** put the purple needle cap back on. It may damage the needle.
- It is normal to see a drop of medicine come out of the needle or injection end of the autoinjector.

Important: Keep your thumb away from the status button until you are ready to inject.



12 With the progress bar facing you, place and hold the autoinjector on the injection site.

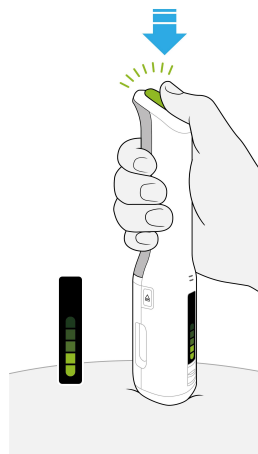
- After placing on the skin, wait for the:
 - status button to turn green,
 - progress bar to turn green, and
 - chime sound (will not chime if sound switch is off).
- **Do not** stretch or pinch the injection site.



If the status button does not turn green, see the User Manual, section "Troubleshooting."

Be patient.

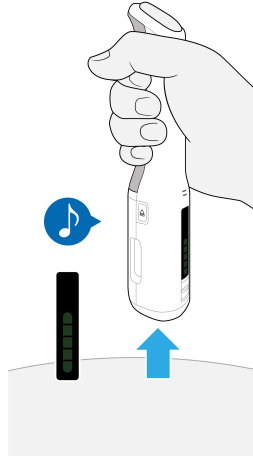
The injection may take up to **20 seconds**.



13 Press and release the status button to inject.

- **Do not** lift the autoinjector from the skin until the injection is complete.
- During the injection:
 - the green status button will flash on and off,
 - the progress bar lights will decrease, and

- o you will hear a motor noise.
- The injection may take up to 20 seconds to complete.

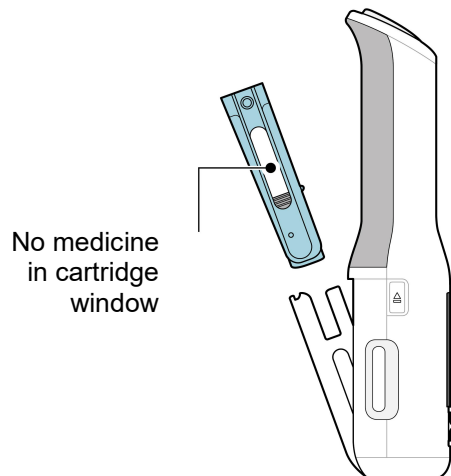


14 Keep holding flat on the skin until the status button and progress bar turn off.

- The injection is complete when the:
 - o status button turns off,
 - o progress bar turns off, and
 - o chime sounds (will not chime if sound switch is off).
- Lift it from the skin when the injection is complete.
- **Do not** block the door, it will open automatically.

Important: When you remove the autoinjector, if the status button is flashing red either see the User Manual, section "Troubleshooting" or call 1-888-4ENBREL (1-800-436-2735).

Completing the Injection



15 Remove the used cartridge and confirm a full dose of medicine was injected.

- When the door opens, remove the used cartridge and close the door.
- A small drop of liquid on the injection site is okay.

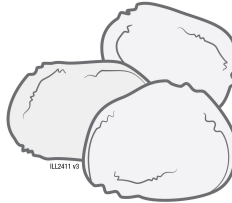
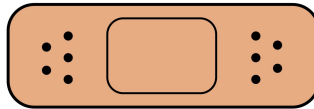
Important: If it looks like the medicine is still injecting or if you see medicine in the cartridge window, this means you may not have received a full dose. Call your healthcare provider right away.



16 Place the used cartridge and purple needle cap in an FDA-cleared sharps disposal container.

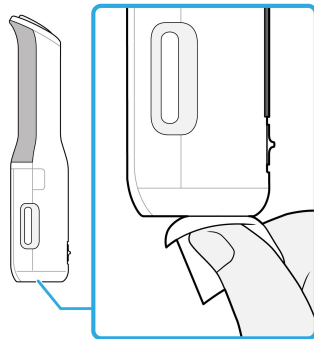
- **Do not** reuse the cartridge.
- **Do not** throw away the cartridge in your household trash.
- Small parts such as the purple needle cap may cause a choking hazard for children and pets.

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



17 Check the injection site.

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



18 Clean the injection end of the autoinjector with a new alcohol wipe and let it dry.

- Store the autoinjector at room temperature in a dry, safe place such as in a cabinet or drawer.
- **Do not** store the autoinjector in the refrigerator.

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.

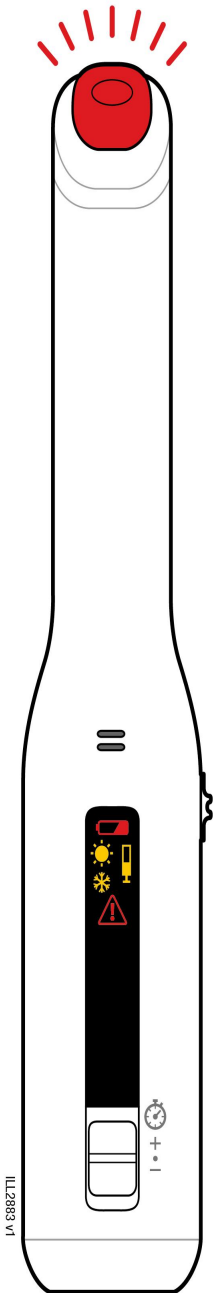
There may be state or local laws about how you should throw away used needles and syringes.

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.



Troubleshooting Error symbols: Why is the status button flashing red?



Low battery:

The battery is running very low. Less than 3 weeks or 3 injections remain. The battery is not replaceable or rechargeable.

Call 1-888-4ENBREL (1-888-436-2735) for a replacement autoinjector.

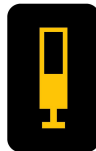
See the User Manual, section "Troubleshooting", for more information.



Needle exposure:

The needle may be exposed and an incomplete dose may have been injected. Look for medicine in the cartridge window. Call your healthcare provider if you feel you have given yourself an incomplete injection. Take special care when removing and handling the cartridge. Place the cartridge in an FDA-cleared sharps disposal container.

See the User Manual, section "Troubleshooting", for more information.



Enbrel Mini problem:

There are several reasons you might get this error.

See the User Manual, section "Troubleshooting", for more information.



Battery dead:

The battery is dead.

Call 1-888-4ENBREL (1-888-436-2735) for a replacement autoinjector.

See the User Manual, section "Troubleshooting", for more information.



Too hot or too cold:

The autoinjector is too hot or too cold. This will lock the door. Place the autoinjector at room temperature in a dry, safe place, and allow it to naturally cool or warm to room temperature. Then try again.

Store the autoinjector in a dry, safe place, such as a cabinet or drawer at 50°F to 104°F (10°C to 40°C).

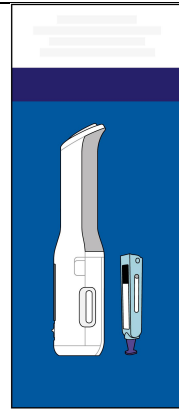
See the User Manual, section "Troubleshooting", for more information.



Autoinjector detected problem:

See the User Manual, section "Troubleshooting", for reset instructions.

See the **User Manual** booklet for more information.



Flip over for additional information



For more information or help call 1-888-4ENBREL (1-888-436-2735).

Important Information You Need to Know Before Injecting ENBREL

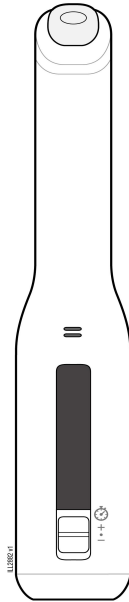
The AutoTouch reusable autoinjector is used with the Enbrel Mini single-dose prefilled cartridge to administer your dose of ENBREL. The Enbrel Mini single-dose prefilled cartridge contains one 50 mg single-dose of ENBREL.

Before you use the AutoTouch reusable autoinjector with Enbrel Mini single-dose prefilled cartridge for use with ENBREL, read this important information:

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- Children must weigh at least 138 pounds to receive 50 mg Enbrel Mini. Children who weigh less than 138 pounds should receive a different form of ENBREL.
- **Do not** use the autoinjector or cartridges if either carton is damaged or either seal is broken.
- The autoinjector and the cartridge are not made with natural rubber latex.
- **Do not** use the autoinjector or cartridge if it has been dropped on a hard surface. Part of the autoinjector or cartridge may be broken even if you cannot see the break.
 - If the cartridge has been dropped, use a new cartridge and call 1-888-4ENBREL (1-888-436-2735).
 - If the autoinjector has been dropped, call for a replacement at 1-888-4ENBREL (1-888-436-2735).

Important: Keep the autoinjector, cartridge, and sharps disposal container out of the sight and reach of children.

AutoTouch[®] Reusable Autoinjector Storage and Handling



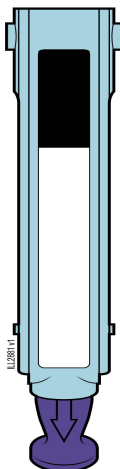
- Store the autoinjector at room temperature in a dry, safe place, such as a cabinet or drawer at 50°F to 104°F (10°C to 40°C).
- **Do not** store the autoinjector in the refrigerator with the cartridge.
- Use an alcohol wipe to clean the bottom (injection end) before and after each use.



See the User Manual, section "Storage & Handling", for additional information.

For more information or help, call 1-888-4ENBREL (1-888-436-2735).

Enbrel Mini[®] Cartridge Storage and Handling



- Keep the cartridge which contains ENBREL, in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, you may store the cartridge at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days.
- **Do not** put the cartridge back in the refrigerator once it reaches room temperature.
- Record the date you removed the cartridge from the refrigerator and use it within 30 days.
- **Do not** store the cartridge in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- **Do not** freeze the cartridge.
- **Do not** shake the cartridge at any time.
- Keep the cartridge in the original carton to protect it from light or physical damage.
- **Do not** remove the purple needle cap from the cartridge until it is inside the autoinjector and you have reached step 11 in this Instructions for Use.

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

For more information or help call 1-888-4ENBREL (1-888-436-2735).

We're right here, right when you need us.

Personalized patient support designed for you.

AMGEN Support⁺

With financial support resources and other helpful patient services, we are here to help you along the way.

Call 1-888-4ENBREL (1-888-436-2735) or visit enbrel.com/support to find out more.



Scan the QR code for more information

Additional Support

Scan the QR code for some helpful things to know as you get started.



ENBRELinjection.com



Manufactured by:
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U.S. License Number 1132

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