

Front Panel Text

Read these instructions before using an AutoTouch® reusable autoinjector for use with Enbrel Mini® (etanercept) single-dose prefilled cartridge.

Side 1 Text

Your healthcare provider has prescribed Enbrel® AutoTouch reusable 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. Call your healthcare provider if you or your caregiver has any questions about the right way to inject Enbrel.

Read these instructions before using an AutoTouch reusable autoinjector for use with Enbrel Mini (etanercept) single-dose prefilled cartridge.

Speed switch

Changing injection speed

The AutoTouch reusable autoinjector allows you to choose the speed of your injection. You can try the three speeds to decide which speed is most comfortable for you.

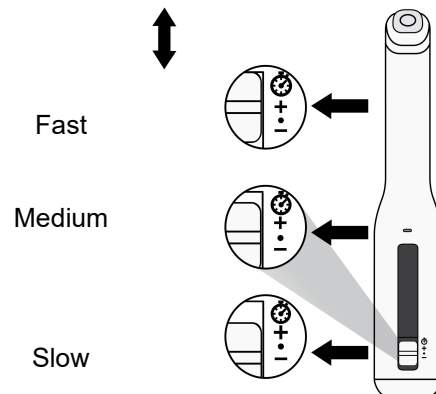
- Three speed settings are available: Fast, Medium, and Slow.
- The factory setting is set to Medium, the black dot (•).

To change the injection speed:

- For a **faster** injection, move the speed switch **up to the plus sign (+)**.
- For a **slower** injection, move the speed switch **down to the minus sign (-)**.

NOTE: When you receive your AutoTouch reusable autoinjector, the speed will be set to Medium (•). Set the injection speed **before** you place the autoinjector on your skin and press the start button. The injection speed cannot be changed after you begin an injection.

Speed switch moves up or down to adjust speed



Sound switch

Turning sounds off

The AutoTouch autoinjector makes sounds (♪) to help guide your injection. When you receive a new autoinjector, it will be set with the sounds on (sound switch down).

- To turn off these sounds, slide the sound switch up (red bar is visible).
- Even when the sound is turned off, you will still hear the noise of the motor during the injection and will hear any error alerts to warn you there is a problem. See (Troubleshooting: Error symbols) below if you receive any error alerts.

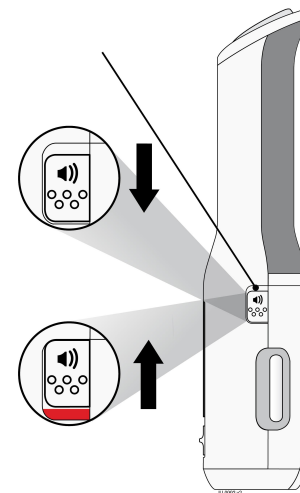
Sound Switch

Sounds on

Slide switch down

Sounds off

Slide switch up (red bar is visible)

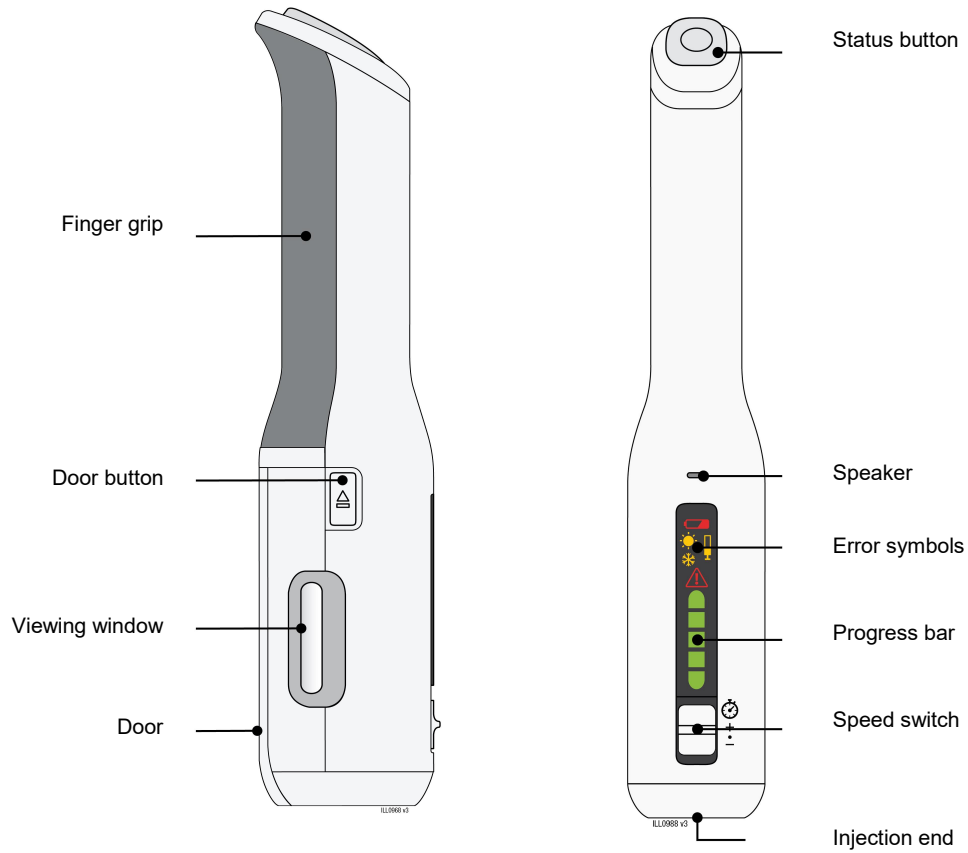


Turn over for step-by-step INSTRUCTIONS FOR USE and other information.

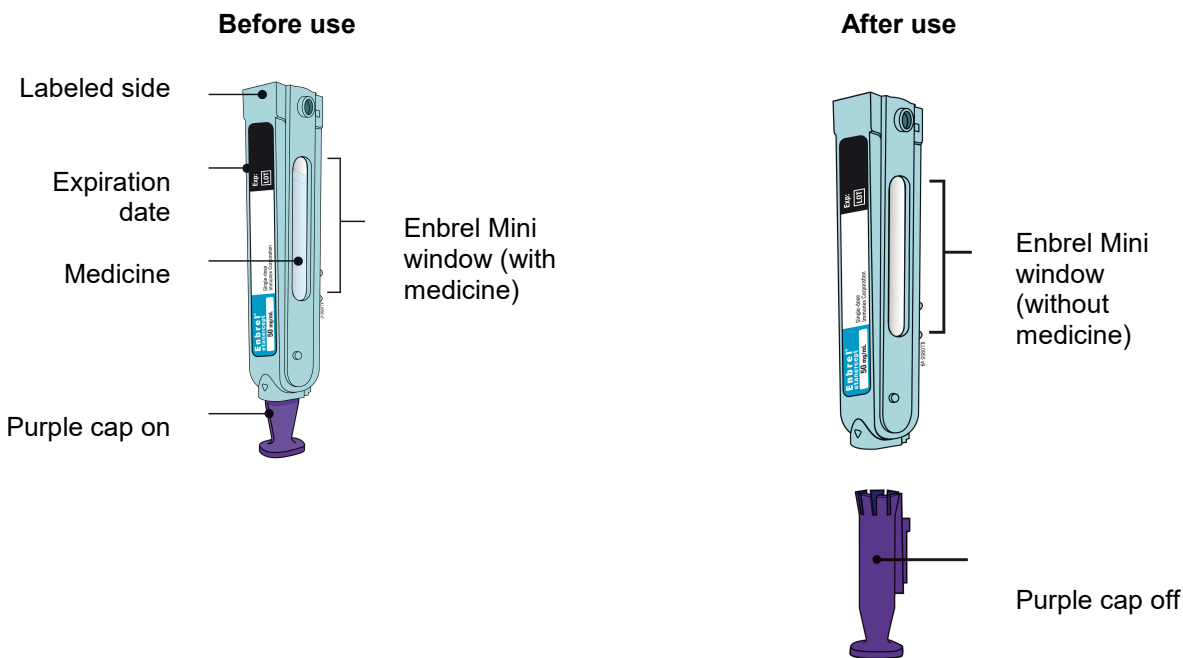
INSTRUCTIONS FOR USE
ENBREL® (en-brel)
(etanercept)
injection, for subcutaneous use
Enbrel Mini® Single-dose Prefilled Cartridge
for use with all AutoTouch® Reusable Autoinjectors

Guide to parts

AutoTouch reusable autoinjector



Enbrel Mini® single-dose cartridge



Important: The needle is inside Enbrel Mini.

Important

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:

Storing your Enbrel Mini single-dose cartridges:

- Store Enbrel Mini, which contains Enbrel, in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, you may store Enbrel Mini at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days.
 - Once Enbrel has reached room temperature, do not put it back in the refrigerator.
- Throw away (dispose of) Enbrel Mini that has been stored at room temperature after 30 days.
- **Do not store Enbrel Mini in extreme heat or cold.** For example, avoid storing in your vehicle's glove box or trunk.
- **Do not freeze.**
- **Do not shake.**
- Store Enbrel Mini in the original carton to protect from light or damage.

Using your Enbrel Mini single-dose cartridges:

- 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 Enbrel Mini after the expiration date printed on the label.
- **Do not** shake Enbrel Mini.
- **Do not** remove the purple cap from Enbrel Mini until it is inside the AutoTouch reusable autoinjector and you are ready to inject.
- **Do not** use Enbrel Mini if it has been dropped on a hard surface. Part of Enbrel Mini may be broken even if you cannot see the break. Use a new Enbrel Mini cartridge, and call 1-888-4Enbrel (1-888-436-2735).
- The AutoTouch reusable autoinjector and the Enbrel Mini cartridge are not made with natural rubber latex.
- 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.

Storing your AutoTouch reusable autoinjector:

- Store AutoTouch 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).
- Use an alcohol wipe to clean the bottom (injection end) before and after each use.
- **Do not** store AutoTouch in the refrigerator with Enbrel Mini.

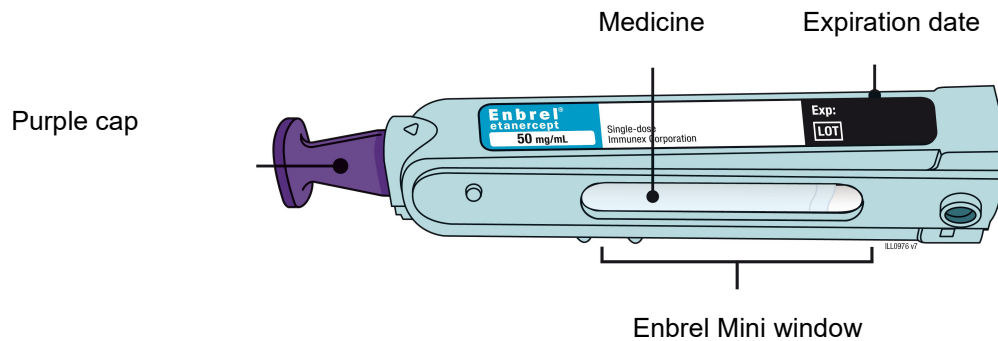
Keep Enbrel Mini and AutoTouch and all medicines out of the reach of children.

For more information or help, visit www.enbrel.com or call 1-888-4Enbrel (1-888-436-2735). Read your AutoTouch User Manual for additional care and storage information.

Step 1: Prepare

- A** Remove one Enbrel Mini® single-dose cartridge from the carton.
- Put the carton containing any unused Enbrel Mini back in the refrigerator.
 - Leave Enbrel Mini at room temperature for at least 30 minutes before injecting.
 - **Do not** put Enbrel Mini back in the refrigerator once it has reached room temperature.
 - **Do not** try to warm Enbrel Mini by using a heat source such as hot water or microwave.
 - **Do not shake** Enbrel Mini.
 - **Do not remove** the purple cap from Enbrel Mini yet.

B Inspect the Enbrel Mini single-dose prefilled cartridge.



Make sure the medicine in the window is clear and colorless. It is okay if you see small white particles in the medicine window.

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

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

C Gather all materials you need for your injection.

Wash your hands thoroughly with soap and water.

Place the following on a clean, well-lit, flat surface:

- AutoTouch®
- 1 Enbrel Mini®
- 3 alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



AutoTouch



Enbrel Mini cartridge



3 Alcohol wipes



Cotton ball or gauze pad



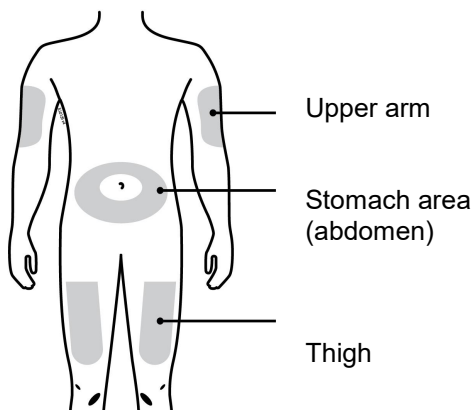
Adhesive bandage



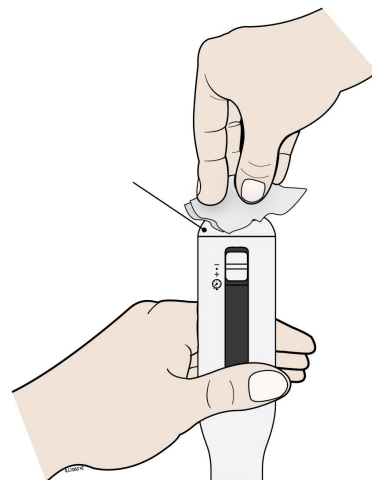
Sharps disposal container

D Prepare and clean your injection site.

Also clean the injection end of the AutoTouch® with a new alcohol wipe.



Injection end



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

You can use:

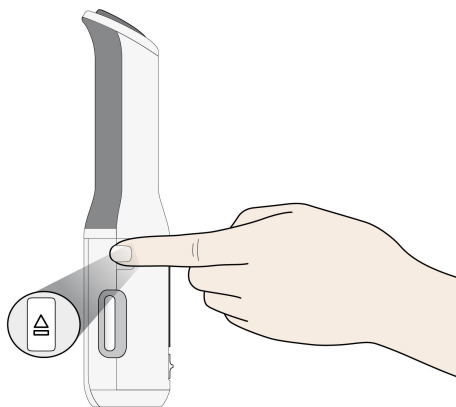
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)

Important:

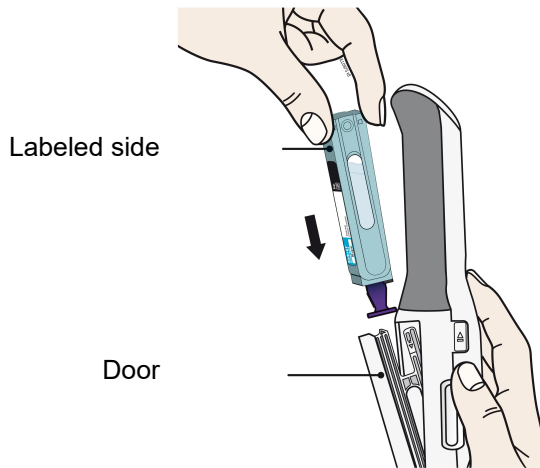
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin 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 patches or lesions.

Step 2: Get ready

E Press the door button to open the door.



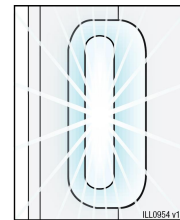
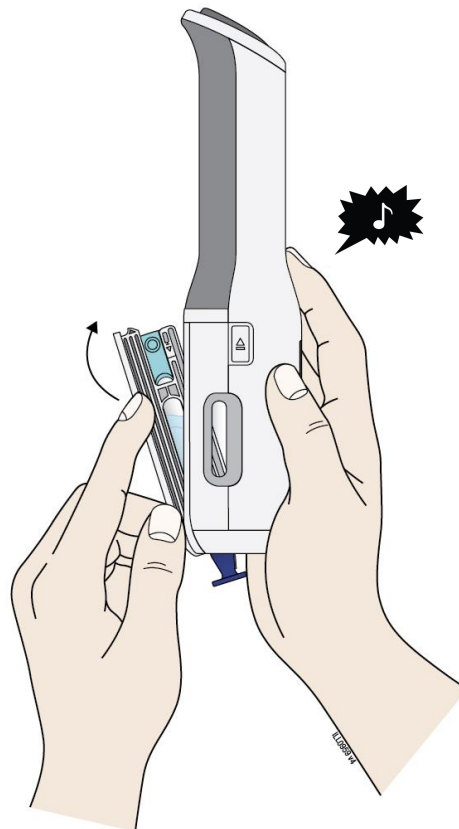
F Hold the Enbrel Mini® single-dose cartridge with the labeled side facing out and slide into door.



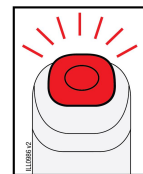
Hold with the labeled side facing out and the purple cap pointing down. Then slide Enbrel Mini into the door. It will slide all the way down into AutoTouch®.

- **Do not** force Enbrel Mini into AutoTouch if it does not slide in easily. Check that it is positioned correctly inside AutoTouch.

G Close the door.



AutoTouch® is awake
when light is on in
viewing window

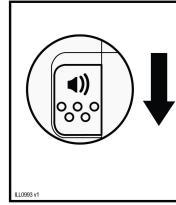


If you see a red
status button call
1-888-4Enbrel
(1-888-436-2735)

When you see the viewing window light up and hear a “chime”, this means that Enbrel Mini® has been loaded properly. AutoTouch is now in the awake mode.

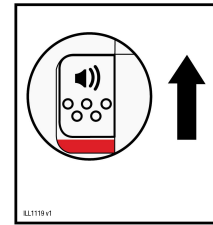
Note: If the sound switch is set to the “sounds off” position, you will not hear this sound. To turn the “sounds on”, slide the sound switch down. The red bar will no longer be visible.

Sounds on



Slide switch down

Sounds off



Slide switch up

Important: Do not remove the purple cap until you are ready to give your injection.

Step 3: Inject



Read the following information before proceeding with your injection.

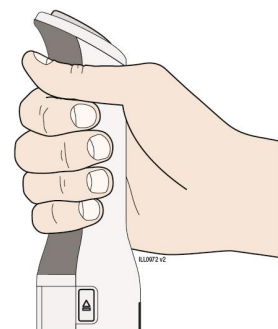
You will now be performing the following tasks in order:

- Hold AutoTouch® correctly.
- Remove the purple cap.
- Confirm that AutoTouch is “awake”.
- Place and hold AutoTouch on the injection site.
- After the status button turns green, press the status button to start the injection.
- Wait for the injection to finish (ensure that AutoTouch maintains full contact with the skin).
- Confirm the injection is complete.

Do not give your injection until you have read these instructions and feel comfortable with how to use AutoTouch the right way.

H Hold the AutoTouch reusable autoinjector with fingers wrapped around the gray finger grip as shown.

- Before placing AutoTouch on your skin, make sure that AutoTouch is “awake”. Look to see that the viewing window light is on. If the viewing light is off this means it is in “sleep mode”, press the status button to “wake it up”.



I When you are ready to inject, pull the purple cap straight down and off. **Do not** leave the purple cap off for more than 5 minutes. This can dry out the medicine.

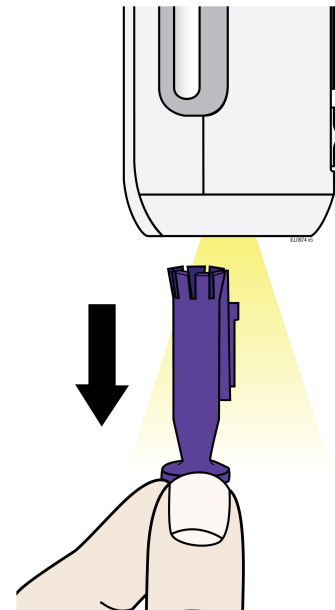
Dispose of the purple cap in a sharps disposal container. Small parts such as the purple cap may cause a choking hazard for children and pets.

- The AutoTouch® site light will turn on to help you see the injection site.

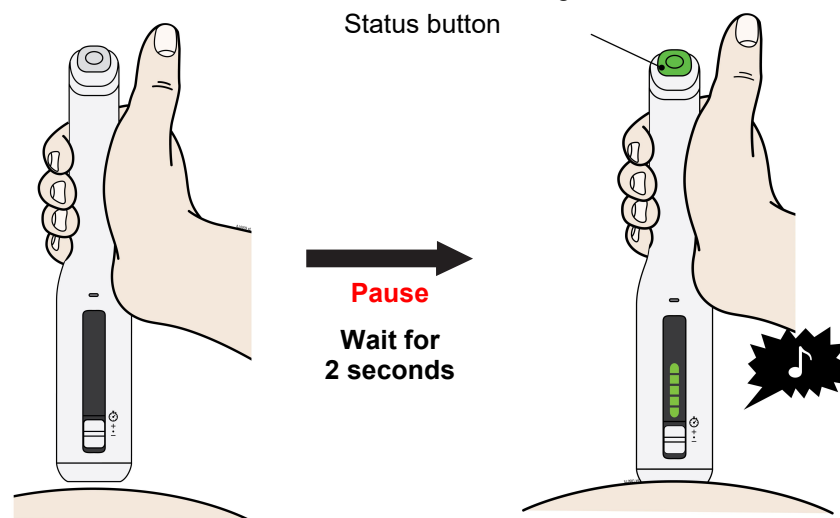
It is normal to see a drop of liquid at the end of Enbrel Mini® needle or bottom of AutoTouch.

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

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



J Place and hold on the skin. Wait for the status button to turn green and a chime to sound.

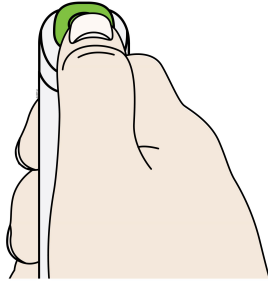


Gently place and hold the AutoTouch® reusable autoinjector on your skin and wait 2 seconds for the status button to turn green. You will hear a “chime” (unless the sound switch is set to the “sounds off” position).

- Keep your thumb off the status button during this step.
- **Do not** press the autoinjector hard on your skin. There is no need to stretch or pinch your skin.

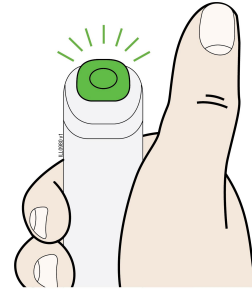
- K** Press and release the status button. The status button will start to flash green. You will hear a click when the injection starts.

Press



→
Status button
flashes green

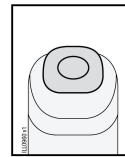
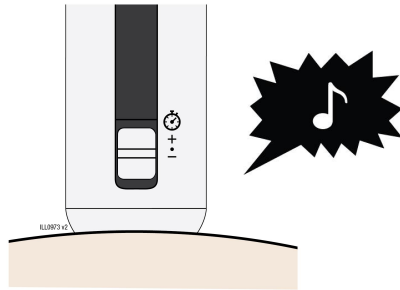
Release



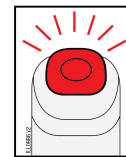
The green status button means your injection has started. You will hear a motor noise and the status button will flash green.

Important: Do not lift AutoTouch® off your skin while the injection is in progress. Continue to hold AutoTouch straight and steady.

- L** The injection is finished when the green light turns off and a “chime” sounds. Check to make sure you do not see a red status button.



(light off)
Injection
finished

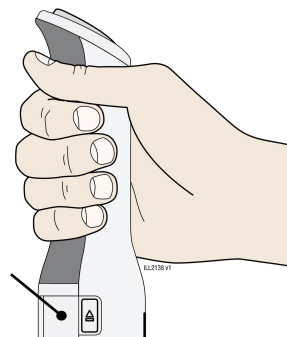


(red light on)
Injection error
Call 1-888-4Enbrel
(1-888-436-2735)

Lift AutoTouch® off your skin.

When your injection is finished, you will hear a motor noise for a few seconds. When finished, the door will automatically open. Do not block the door with your hand.

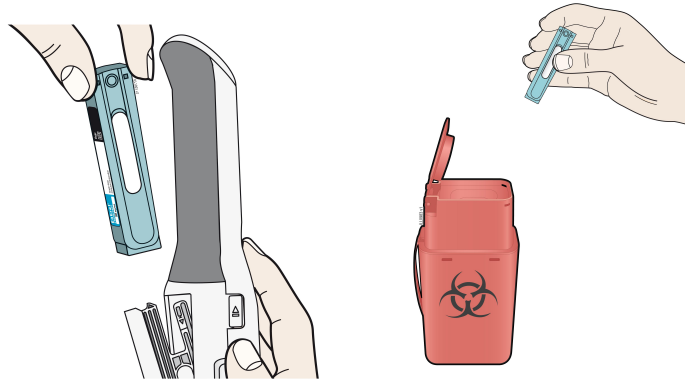
Door



Important: When you remove AutoTouch, if the status button has turned red, call 1-888-4Enbrel (1-888-436-2735). If it looks like the medicine is still injecting or if you see medicine in the Enbrel Mini® window, this means you may not have received a full dose. Call your healthcare provider right away.

Step 4: Finish

M Remove and throw away (dispose of) the Enbrel Mini® single-dose prefilled cartridge.



When the door opens, remove Enbrel Mini, close the door, then put it in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) Enbrel Mini 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** reuse Enbrel Mini.
- **Do not** recycle Enbrel Mini or the sharps disposal container or throw them into household trash.

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

N 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.

O Clean and store the AutoTouch® reusable autoinjector.

Clean the injection end of the autoinjector with a new alcohol wipe and allow to dry.

Store AutoTouch at room temperature in a dry, safe place such as in a cabinet or drawer.

Important: **Do not** store AutoTouch in the refrigerator.

Troubleshooting: Error symbols

Why is the status button flashing red?



Low battery: The battery is very low. Only a few injections remain. Note: battery icon may be yellow on some devices. Call 1-888-4Enbrel (1-888-436-2735) for a replacement AutoTouch reusable autoinjector.



Battery dead: The battery is dead. Note: battery icon may be yellow on some devices. Call 1-888-4Enbrel (1-888-436-2735) for a replacement AutoTouch reusable autoinjector.



Too hot or too cold: AutoTouch reusable autoinjector is too hot, or too cold. Allow to naturally cool or warm to room temperature until symbols are gone.



Enbrel Mini® problem: There are several reasons you might get this error. See the User Manual for more information or call 1-888-4Enbrel (1-888-436-2735).



Needle exposure: The needle may be exposed and an incomplete dose may have been injected. Look for medicine in Enbrel Mini. Call your healthcare provider if you feel you have given yourself an incomplete injection. Take special care when removing and handling Enbrel Mini by disposing properly in the sharps container.



AutoTouch reusable autoinjector failure: Call 1-888-4Enbrel (1-888-436-2735) for reset instructions or a replacement AutoTouch reusable autoinjector.



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

AMGEN®

Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

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