

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>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.

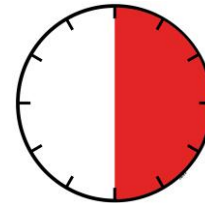
Before you inject, always check the label of the autoinjector to make sure you have the correct medicine and the correct dose of ENBREL.

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.

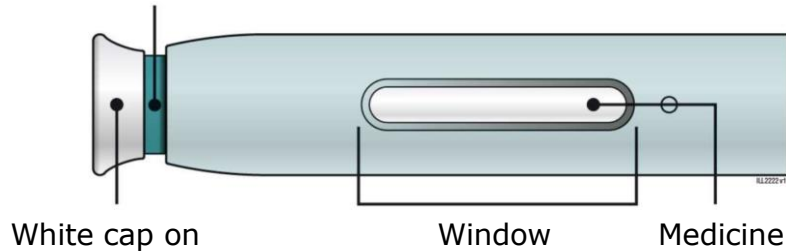
30 minutes



- **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**)



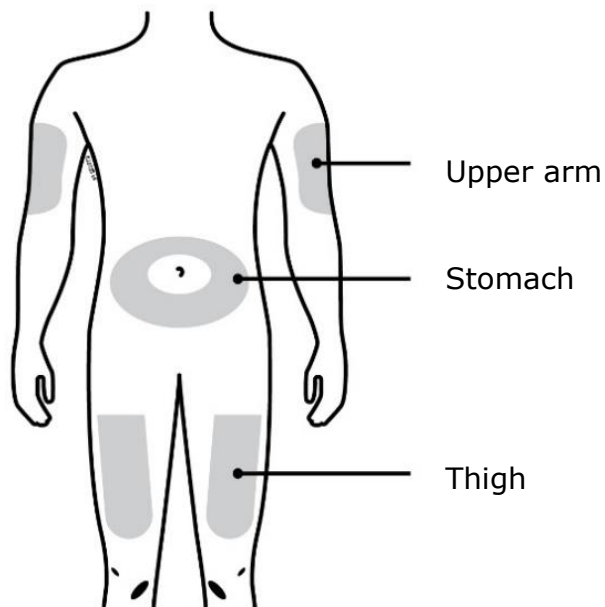
1D Prepare and clean your injection site.

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.

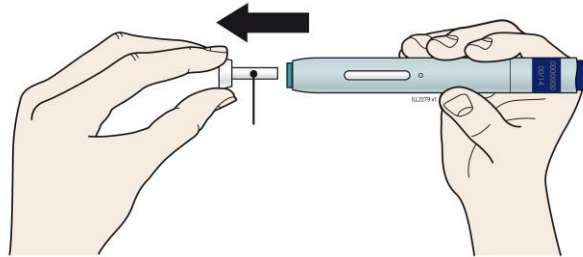
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot you used for the last injection.
- **Do not** inject into areas where the skin is tender, bruised, red,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



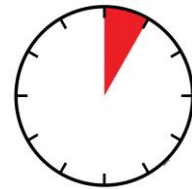
Step 2: Get ready

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

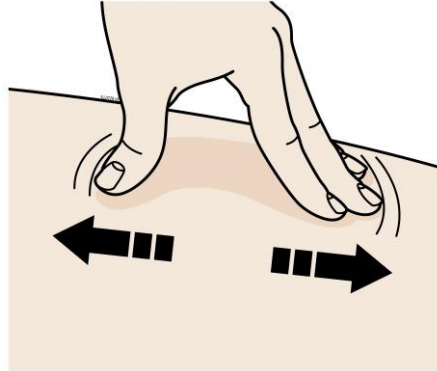
It is normal to see a drop of liquid at the end of the needle or green safety guard.

- **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.

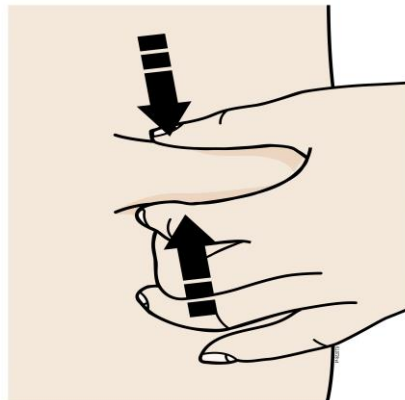
Stretch method:



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

OR

Pinch method:

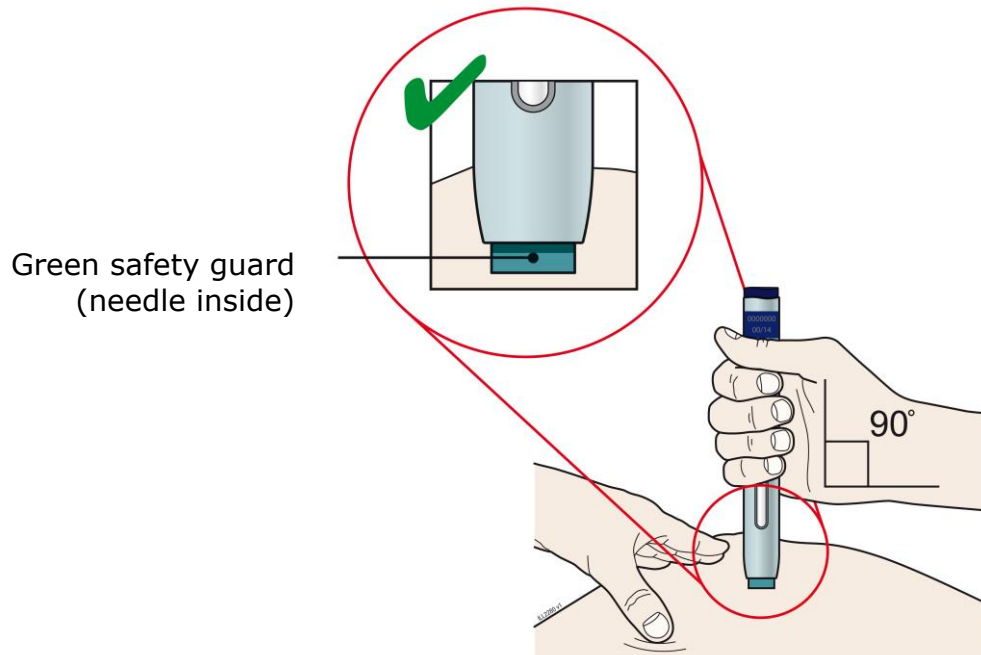


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

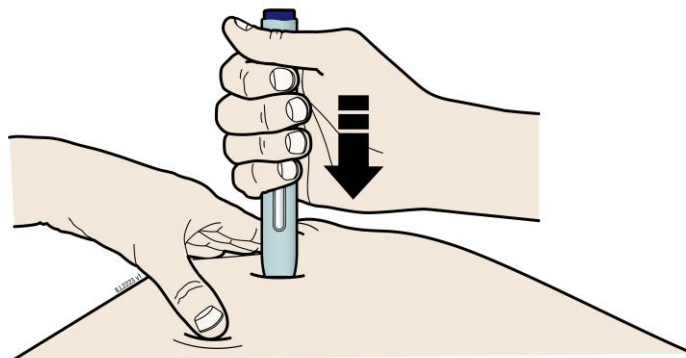
Important: Keep skin stretched or pinched while injecting.

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.

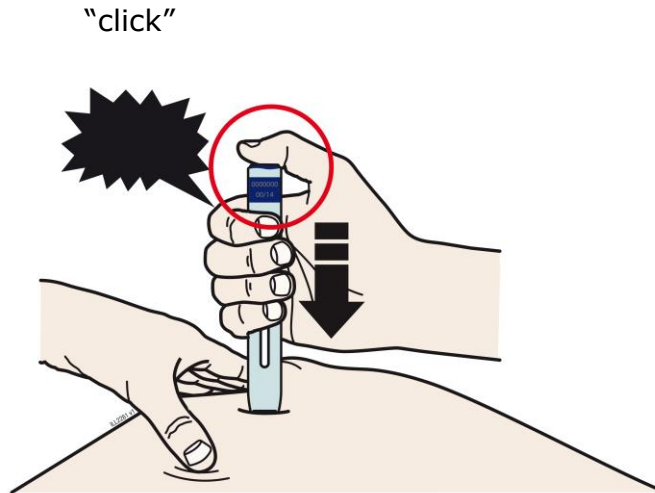


3B Firmly **push** down the autoinjector onto the skin until it stops moving.

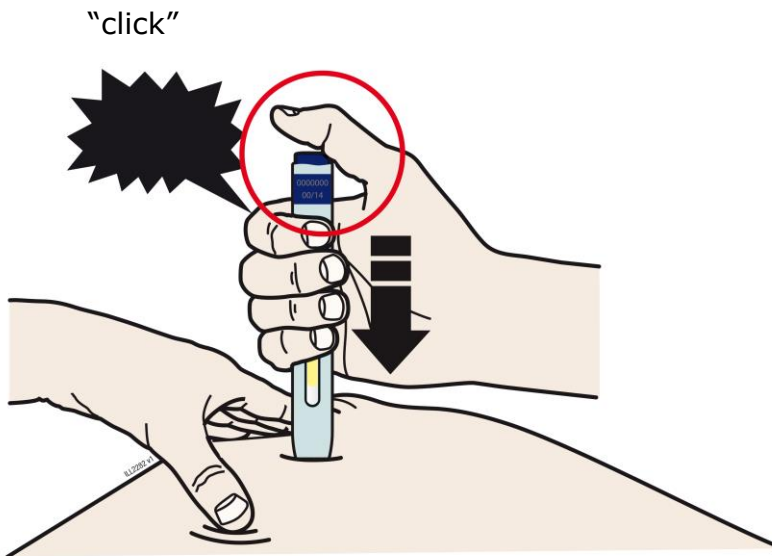


Important: You must push all the way down but **do not** touch the purple start button until you are ready to inject.

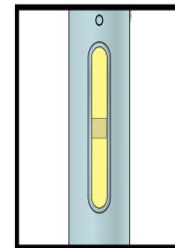
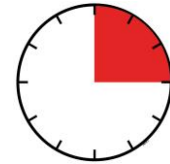
3C When you are ready to inject, **press** the purple start button. You will hear a click.



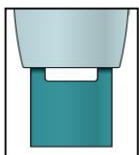
3D Keep **pushing** the autoinjector down on your skin. Then lift your thumb while still holding the autoinjector on your skin. Your injection could take about 15 seconds to complete.



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.

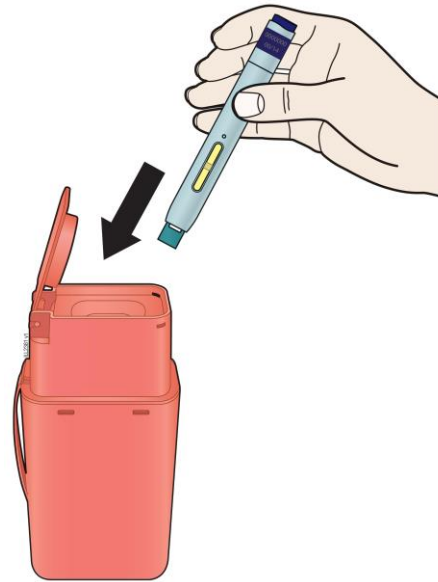
Step 4: Finish

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.



Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

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<part number> Revised: 8/2022 v17



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

How do I prepare and give an injection with Enbrel Single-dose Prefilled Syringe?

There are 2 types of Enbrel single-dose prefilled syringes:

- The 50 mg/mL single-dose prefilled syringe that contains one 50 mg dose of Enbrel.
- The 25 mg/0.5 mL single-dose prefilled syringe that contains one 25 mg dose of Enbrel.

Your healthcare provider will tell you which one to use.

A 50 mg dose can be given as one injection using a 50 mg/mL single-dose prefilled syringe or as two injections using 25 mg/0.5 mL single-dose prefilled syringes. Your healthcare provider will tell you whether the two injections with 25 mg/0.5 mL single-dose prefilled syringes should be given on the same day once a week or on two different days (3 or 4 days apart) in the same week.

Children must weigh at least 138 pounds to use the Enbrel 50 mg/mL single-dose prefilled syringe. Children who weigh less than 138 pounds should use a different form of Enbrel. The Enbrel 25 mg/0.5 mL single-dose prefilled syringe should not be used in pediatric patients weighing less than 68 pounds.

Important: The needle cover on the single-dose prefilled syringe is composed of dry natural rubber, which is made from latex. Tell your healthcare provider if you are allergic to latex.

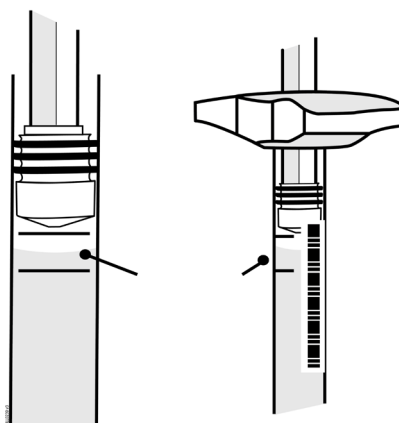
Storage of your Enbrel prefilled syringe

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

Step 1: Setting Up for an Injection

1. Select a clean, well-lit, flat work surface, such as a table.
2. Take the Enbrel carton containing the prefilled syringes out of the refrigerator and place it on your flat work surface. Remove one prefilled syringe and place it on your work surface. Carefully lift the prefilled syringe straight up out of the box. **Do not shake** the prefilled syringe of Enbrel. Place the carton containing any remaining prefilled syringes back into the refrigerator at 36°F to 46°F (2°C to 8°C).
3. Check the expiration date on the prefilled syringe. If the expiration date has passed, **do not** use the prefilled syringe and contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.
4. **Do not** use the prefilled syringe if the needle cover is missing or not securely attached. Call 1-888-4ENBREL (1-888-436-2735).
5. For a more comfortable injection, leave the prefilled syringe at room temperature for about 15 to 30 minutes before injecting. **Do not** remove the needle cover while allowing it to reach room temperature. **Do not** warm Enbrel in any other way (for example, **do not** warm it in a microwave or in hot water).
6. Hold the prefilled syringe with the covered needle pointing down. If bubbles are seen in the syringe, very gently tap the prefilled syringe to allow any bubbles to rise to the top of the syringe. Turn the syringe so that the purple horizontal lines on the barrel are directly facing you. Check to see if the amount of liquid in the syringe falls between the purple lines. The top of the liquid may be curved. If the syringe does not have the right amount of liquid, **do not** use that syringe. Contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.

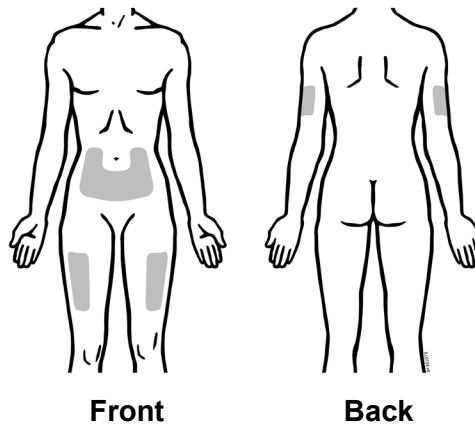


Fill Level Indicator

7. Assemble the additional supplies you will need for your injection. These include an alcohol swab, a cotton ball or gauze, and a sharps disposal container (see “**Step 4: Disposing of Supplies**”).
8. Wash your hands with soap and warm water.
9. Make sure the solution in the prefilled syringe is clear and colorless. You may notice small white particles in the solution. These particles are formed from Enbrel and this is acceptable. However, **do not inject the solution if it is cloudy or discolored, or contains large or colored particles**, call 1-888-4ENBREL (1-888-436-2735).

Step 2: Choosing and Preparing an Injection Site

1. Recommended injection sites for Enbrel using a prefilled syringe include:
 - the front of the middle thigh
 - the stomach area (abdomen), except for the 2-inch area right around the navel (belly button)
 - the outer area of the upper arm (only if someone else is giving you the injection)

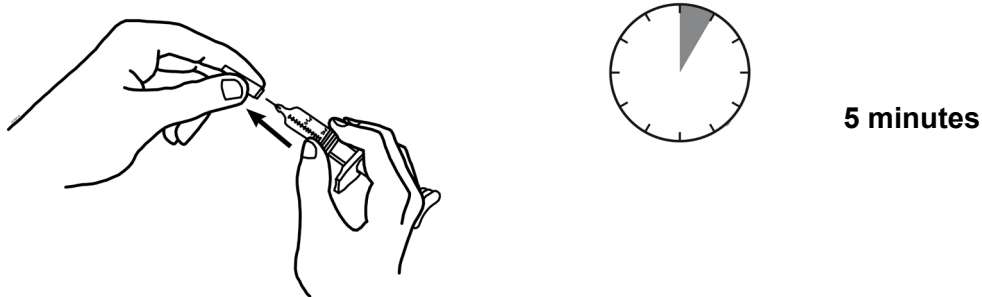


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area of skin where Enbrel is to be injected, wipe the injection site with an alcohol swab. **Do not touch this area again before giving the injection.**

Step 3: Injecting Enbrel Using a Prefilled Syringe

Do not remove the needle cover from the prefilled syringe until you are ready to inject.

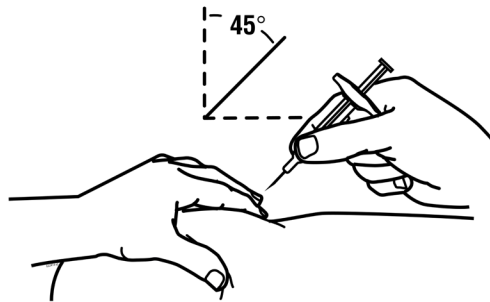
1. Pick up the prefilled syringe from your flat work surface. Hold the barrel of the prefilled syringe with one hand and pull the needle cover straight off, only when you are ready to inject. **Do not** leave the needle cover off for more than **5 minutes**. This can dry out the medicine.



To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it, and **do not** try to put the needle cover back onto the prefilled syringe.

When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. **Do not** touch the needle or allow it to touch any surface. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out.

2. Holding the syringe with the needle pointing up, check the syringe for air bubbles. If there are bubbles, **gently** tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.
3. Holding the syringe in one hand like a pencil, use the other hand to gently pinch a fold of skin at the cleaned injection site and hold it firmly.
4. With a quick and “dart-like” motion, insert the needle at a 45-degree angle into the skin.



5. When the needle is completely inserted into the skin, let go of the skin that you are holding. With your free hand, hold the syringe near its base to stabilize it. Then push the plunger to inject all of the Enbrel solution at a slow, steady rate.

6. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds. **Do not** rub the injection site. If needed, you may cover the injection site with a bandage.

Step 4: Disposing of Supplies

The syringe should **never** be reused. **Never** recap a needle.

- Put the used prefilled syringes in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) prefilled syringes 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 syringes and needles. 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 syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household trash.

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

A healthcare provider familiar with Enbrel should answer all questions. Call 1-888-4ENBREL (1-888-436-2735) or visit www.enbrel.com for more information about Enbrel.

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

AMGEN[®]

Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

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**Instructions for Use
Enbrel® (en-brel)
(etanercept)
injection, for subcutaneous use
single-dose vial**

Read this Instructions for Use before you start taking Enbrel and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition and treatment.

Step 1: Set up



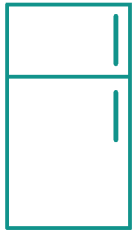
1a. Strength and dose

The strength of the Enbrel single-dose vial is different than the Enbrel multiple-dose vial.

Each single-dose vial contains 25 mg (0.5 mL).

Review your prescription carefully for dose and dosing schedule. Only inject Enbrel after you or your caregiver has received training by your healthcare provider. Your healthcare provider will tell you how often you should use Enbrel. **Do not use Enbrel more often than directed by your healthcare provider.** If you forget to use Enbrel, inject your dose right away. Inject your next dose at your regular scheduled time. If you do not know when to inject Enbrel, call your healthcare provider or pharmacist.

Keep Enbrel out of the reach of children.



1b. Store Enbrel single-dose vials

Store Enbrel in the refrigerator between 36°F to 46°F (2°C to 8°C). You may also store the Enbrel single-dose vials at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days. Throw away Enbrel that has been stored at room temperature after 30 days.

Do not shake.

Do not freeze or store in extreme heat or cold.

Store Enbrel in the original carton to protect from light or damage.

If your dose is
0.5 mL, or LESS

Remove 1 single-dose vial



If your dose is MORE
than 0.5 mL

Remove 2 single-dose vials



1c. Remove correct number of vials

Remove the correct number of Enbrel single-dose vials from the original carton.

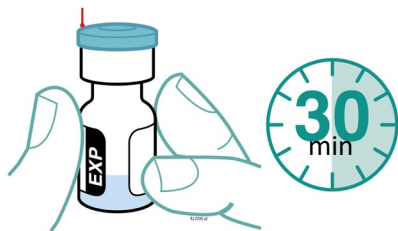
Check your prescription to determine if your dose will require 1 or 2 single-dose vials.

Your dose is determined in milliliters (mL).

Your child's dose of Enbrel depends on his or her weight. Your child's healthcare provider will tell you which form of Enbrel to use and how much to give your child.

Green vial cap

WAIT



1d. Inspect the single-dose vial(s)

Leave the single-dose vial(s) at room temperature, with the green cap(s) on, for at least 30 minutes.

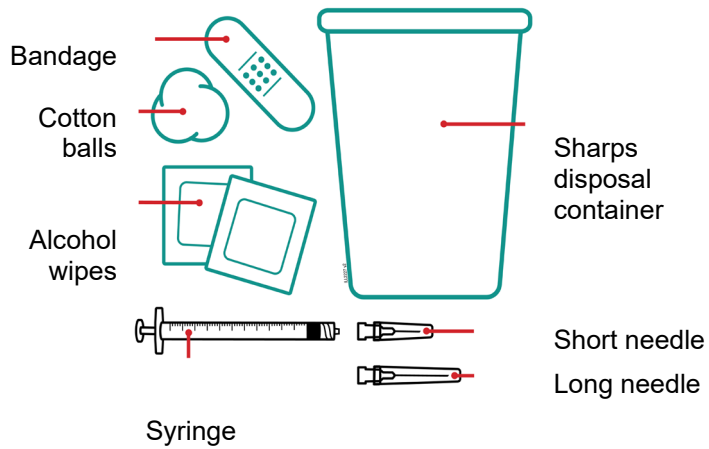
Enbrel is clear and colorless. There may be small white particles in the solution. Check the expiration date.

Keep out of direct sunlight.

Do not use Enbrel if:

- the expiration date has passed
- the green cap is not attached
- it has lumps, is discolored, or is cloudy.

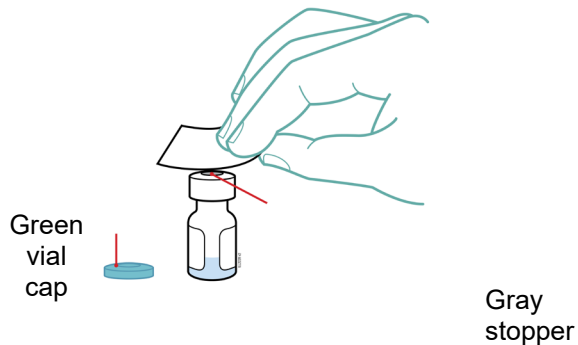
If there are any issues with your Enbrel single-dose vials, please call 1-888-4ENBREL (1-888-436-2735).



1e. Gather all materials and wash hands
Wash your hands with soap and water.

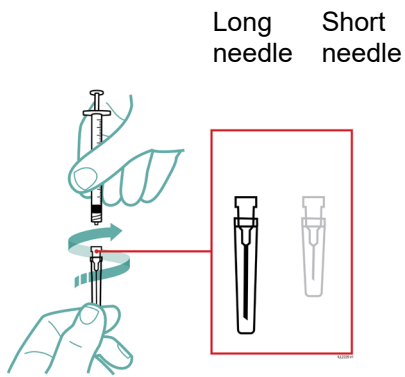
Place the following items on a clean well-lit, flat surface:

- 1 mL syringe
- Long needle: for withdrawal
- Short needle: for injection
- Alcohol wipes
- Cotton balls
- Bandage
- Sharps disposal container



1f. Pop off the green vial cap then wipe the gray stopper
Use an alcohol wipe to clean the gray stopper.

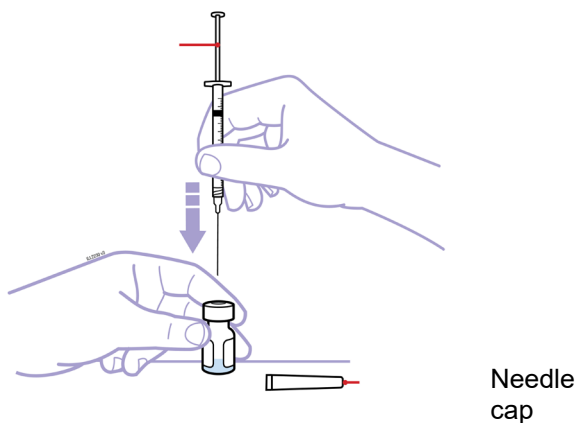
If you require a second single-dose vial, clean the gray stopper of the second single-dose vial with a new alcohol wipe.



1g. Attach the long needle to the syringe
Twist the long needle onto the syringe.

Step 2: Prepare dose

Plunger

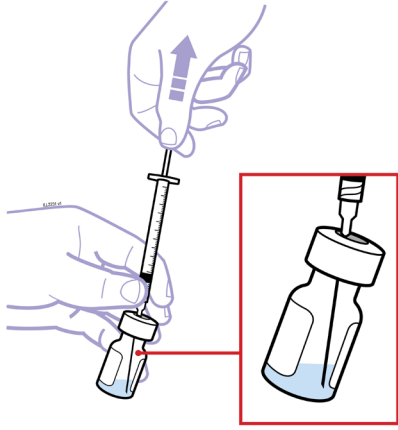


2a. Pull plunger back, insert needle, and push air into single-dose vial
Pull the needle cap straight off and away from your body. Save the needle cap for later.

Pull the syringe plunger back to 0.5 mL.

Hold the single-dose vial on a flat surface with 1 hand. Insert the long needle through the gray rubber stopper above the medicine in the single-dose vial.

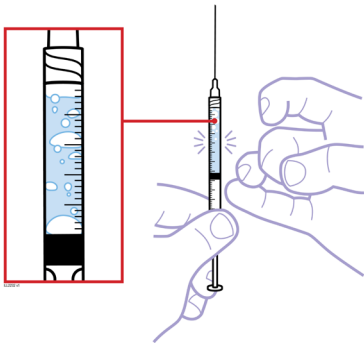
Slowly push 0.5 mL of air into the single-dose vial.



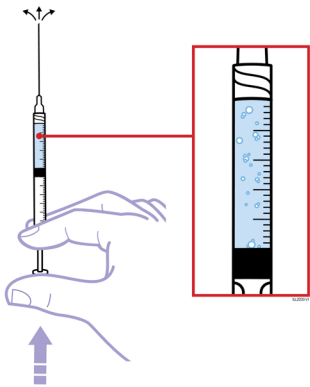
2b. Tilt the single-dose vial to withdraw **all** medicine
Slowly pull back the plunger to fill the syringe **with all the medicine from the single-dose vial**.

Remove needle from the single-dose vial.

The air in the syringe will be removed later.



2c. Gently tap the syringe with fingers to release bubbles
Gently tap the syringe with your fingers to release air pockets and bubbles until they rise to the top of the syringe.

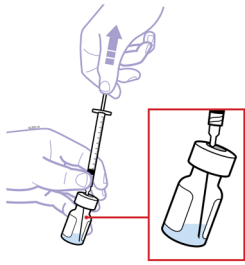


2d. Push out large air pockets and bubbles
After you have gently tapped the large air pockets and bubbles to the top of the syringe, push the plunger up to remove the air out of the syringe.

Small amounts of tiny air bubbles are ok.

If you need 1 single-dose vial, push the plunger to your **total prescribed dose** and continue to step 2g.

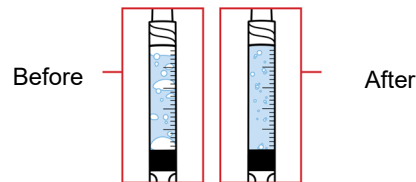
If you need more than 1 single-dose vial to get your **total prescribed dose**, follow these 2 steps:



2e. Insert the same needle in the second vial
Tilt vial to withdraw medicine. Slowly pull back the plunger to fill the syringe **with all medicine from the vial**.

Remove the needle from the single-dose vial.

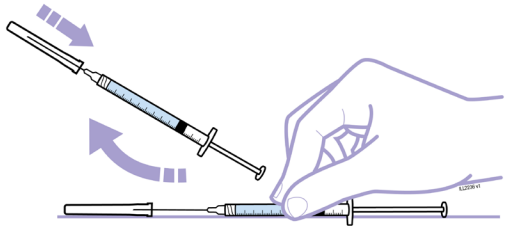
The air will be removed in the next step



2f. Gently tap the syringe to remove the air
Hold the needle pointing up and gently tap the syringe so air bubbles rise to the top.

Push the plunger to **your prescribed dose**.

Small amounts of tiny air bubbles are ok.

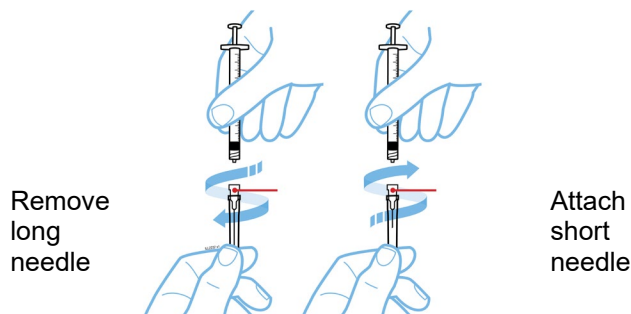


2g. Use 1-handed scoop method to recap
For your safety, place the needle cap on a flat surface.

Using 1 hand, slide the needle into the cap and scoop upwards to cap the needle, without using your other hand.

Then use your other hand to secure the cap and snap into place.

Step 3: Inject and throw away



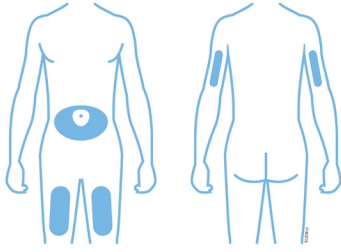
3a. Replace the long needle with the short needle

Twist the long needle off of the syringe.

Throw away the long needle in the sharps disposal container.

Twist the short needle onto the syringe.

Do not remove the needle cover until you are ready to inject.

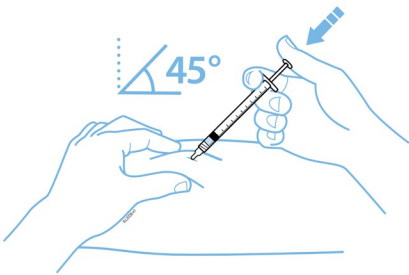


3b. Choose and clean the injection site

- thigh or stomach (avoid 2 inches around the navel)
- back of upper arm (only if someone else is giving the injection)

Choose a different site each time you give yourself an injection. Avoid injecting into tender, raised, red or scaly skin.

Clean the injection site with an alcohol wipe and let dry. **Do not** touch this area again before injecting.



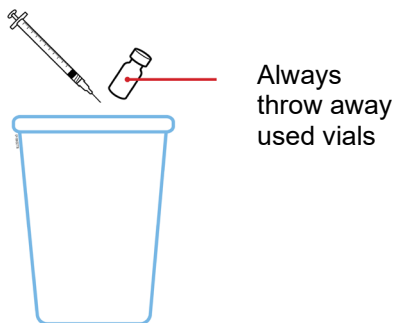
3c. Pinch and inject Enbrel

Gently pinch skin. With a quick firm action, insert the needle into your skin at a 45-degree angle.

When the needle is completely inserted into the skin, slowly push the plunger all the way down.

When the syringe is empty, remove the needle and syringe from your skin. Do not recap the needle.

Do not rub the injection site. If you see drops of blood at the injection site, you can press a cotton ball over the injection site until bleeding has stopped. Apply an adhesive bandage, if needed.



3d. Throw away the used single-dose vials, needles and syringe

Single-dose vials do not contain preservatives and are for **1-time use only**. Unused medicine in the single-dose vials must be thrown away in a sharps disposal container.

Additional disposal information

Do not throw away the vials, needles, and syringe 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
- 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 throw away your sharps disposal container. There may be state or local laws about how you should throw away used vials, 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 throw away 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 vials, syringe, or needles.
- Do not recycle the vials, syringe, needles, or sharps disposal container or throw them into household trash.

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

If you experience any difficulty using your Enbrel single-dose vials, please call 1-888-4ENBREL (1-888-436-2735).

If you have any questions about your Enbrel dosing, please call your healthcare provider.

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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[part number]
Revised: 06/2022 v2

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Front Panel

**Read these instructions before
using Enbrel[®]
Single-Dose Vial
Instructions for Use**

Instructions for Use
Enbrel® (en-brel)
(etanercept)
for injection, for subcutaneous use
Multiple-dose Vial

How do I prepare and give an injection with Enbrel multiple-dose vial?

A multiple-dose vial contains 25 mg of Enbrel.

Storage of Enbrel multiple-dose vial

- Store Enbrel multiple-dose vial in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store Enbrel multiple-dose vial in the original carton to protect from light or physical damage.
- If needed, you may store your Enbrel multiple-dose vial and diluent syringe (dose tray) at room temperature between 68°F to 77°F (20°C to 25°C) for up to 14 days.
 - Once Enbrel multiple-dose vial has reached room temperature, do not put it back in the refrigerator.
- Throw away Enbrel multiple-dose vial that has been stored at room temperature after 14 days.
- Mixed (reconstituted) Enbrel multiple-dose vial should be used right away or kept in the refrigerator at 36°F to 46°F (2°C to 8°C) for up to 14 days.
- **Do not** store Enbrel multiple-dose vial in extreme heat or cold. For example, avoid storing Enbrel multiple-dose vial in your vehicle's glove box or trunk.
- **Do not freeze.**
- **Do not shake.**
- **Keep Enbrel multiple-dose vial and all medicines out of the reach of children.**

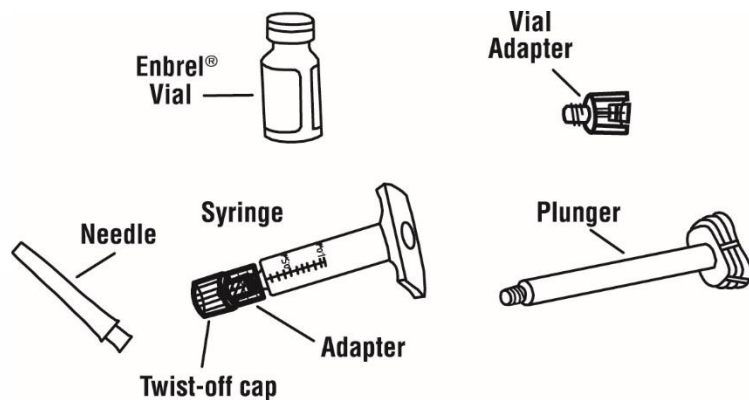
If you have any questions about storage, contact your healthcare provider or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

Step 1: Setting Up for an Injection

1. Select a clean, well-lit, flat work surface, such as a table.
2. Take the Enbrel dose tray out of the refrigerator and place it on your flat work surface.

3. Check the expiration date on the dose tray. If the expiration date has passed, **do not** use the dose tray. Also check to make sure the dose tray has 5 items as pictured below:

- One prefilled diluent syringe containing 1 mL of diluent (liquid) with attached adapter and twist-off cap
- One plunger
- One Enbrel vial
- One 27-gauge ½ inch needle in hard plastic cover
- One vial adapter



If the expiration date has passed, the five items are not included in the dose tray or if any item looks damaged, contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.

4. For a more comfortable injection, leave the dose tray at room temperature for about 15 to 30 minutes before injecting.
5. Wash your hands with soap and warm water.
6. Peel the paper seal off the dose tray and remove all items.
7. Inspect the volume of diluent in the syringe with the twist-off cap pointing down. Use the unit markings on the side of the syringe to make sure there is at least 1 mL of liquid in the syringe. If the level of liquid is below the 1 mL mark, **do not** use. Contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.
8. **Do not** use the syringe if the twist-off cap is missing or not securely attached. Call 1-888-4ENBREL (1-888-436-2735).
9. Two alcohol swabs should be available for the preparation and injection of Enbrel. Alcohol swabs can be found at your local drug store.

Step 2: Preparing the Enbrel Solution

There are two methods for preparing the Enbrel solution. For some children, one vial of Enbrel solution can be used for more than one dose. The free-hand method should be used for children on Enbrel who are using one vial of Enbrel solution for more than one dose. **You should not use the vial adapter method if you will be using the vial more than once.** Ask your healthcare provider if you have questions about which method to use.

- **The Vial Adapter Method**

Adults and larger children on Enbrel may use the vial adapter device to assist with mixing the powder with the liquid and withdrawing Enbrel, and then use a 27-gauge needle to inject the dose. **This method should not be used for children using multiple doses from the same vial of Enbrel.** The instructions for using the vial adapter method are in Step 2A.

- **The Free-Hand Method**

In the free-hand method, a 25-gauge needle is used to assist with mixing the powder with the liquid and withdrawing Enbrel, and a 27-gauge needle is used to inject the dose. Obtain 25-gauge needles from your healthcare provider. Instructions for using the free-hand method are in Step 2B.

The instructions for preparing additional doses from the same vial of Enbrel solution are in Step 3. For each additional dose, you will need two new needles (one 25-gauge needle to withdraw the solution and one 27-gauge needle for injection) and one new empty syringe (1 mL). **Never reuse a syringe or needle.**

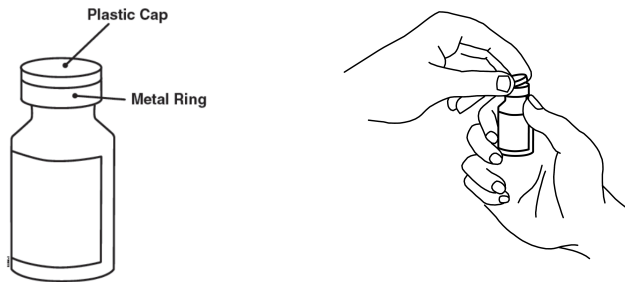
If you are using the vial of Enbrel for more than one dose, you should write the date you mixed the powder and liquid in the area marked "Mixing Date:" on the sticker supplied with these instructions, and attach the sticker to the Enbrel vial.

After you have withdrawn the dose of Enbrel that you need, store the Enbrel vial (in the dose tray) in the refrigerator at 36° to 46°F (2° to 8°C) as soon as possible, but always within 4 hours of mixing the solution. **Do not freeze.** If you have any questions about storage, contact your healthcare provider or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

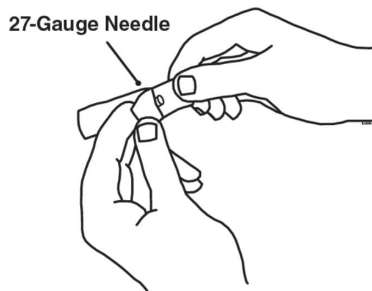
The Enbrel solution must be used within 14 days of the mixing date. You should discard the Enbrel vial and any remaining solution if it is not used within 14 days. **Do not** mix any remaining liquid in one vial of Enbrel solution with another.

STEP 2A: Vial Adapter Method

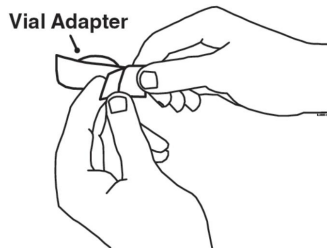
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial.



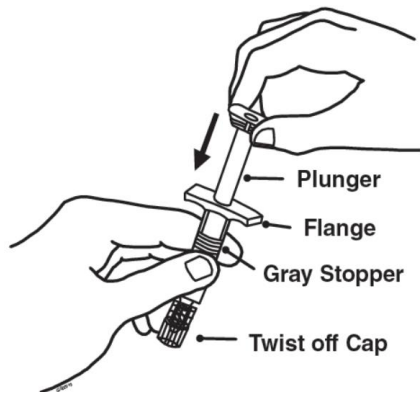
2. Place the Enbrel vial on your flat work surface or turn your dose tray upside down and place your Enbrel vial in the round space marked "V". Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use.



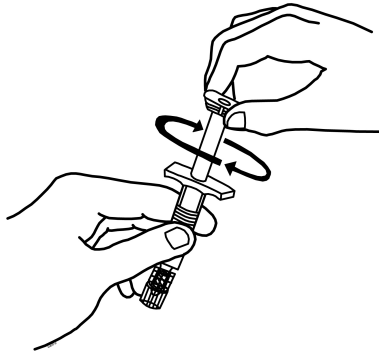
4. Open the wrapper that contains the vial adapter by peeling apart the tabs and set the vial adapter aside for later use. **Do not** touch the vial adapter's twist-on end or the spike inside.



- Slide the plunger into the flange end of the syringe.



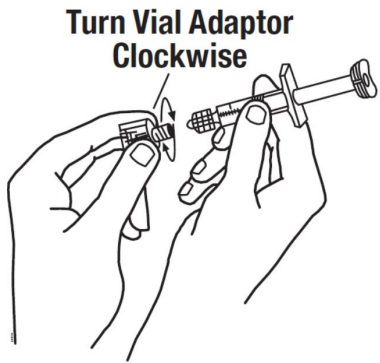
- Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



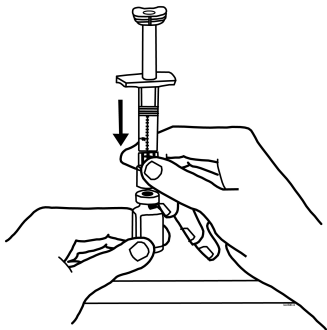
- Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch the syringe tip.



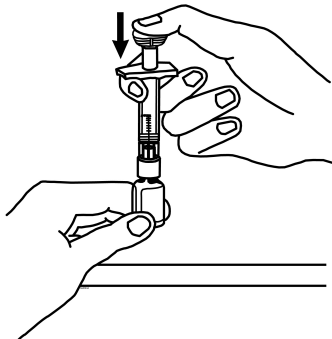
- Once the twist-off cap is removed, pick up the vial adapter with your free-hand. Twist the vial adapter onto the syringe, turning clockwise until you feel a slight resistance. **Do not over-tighten.**



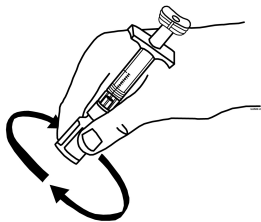
9. Hold the Enbrel vial upright on your flat work surface. Grasp the sides of the vial adaptor and place it over the top of the Enbrel vial. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. Insert the vial adaptor into the gray stopper on the Enbrel vial. The plastic spike inside the vial adaptor should puncture the gray stopper. The vial adaptor should fit snugly.



10. Hold the Enbrel vial upright on your flat work surface and push the plunger down until all the liquid from the syringe is in the Enbrel vial. You may see foaming (bubbles) in the vial. This is normal.

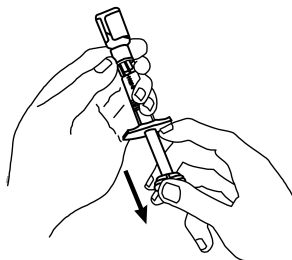


11. Gently swirl the Enbrel vial in a circular motion to dissolve the powder. If you used the dose tray to hold your Enbrel vial, take the vial (with the vial adaptor and syringe still attached) out of the dose tray, and gently swirl the vial in a circular motion to dissolve the powder.

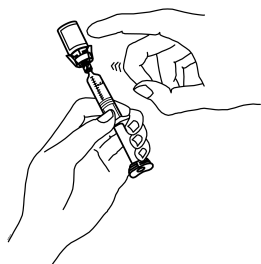


Do not shake. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do not inject the solution if it is discolored, contains lumps, flakes, or particles.** If all the powder in the Enbrel vial is not dissolved or there are particles present after 10 minutes, call 1-888-4ENBREL (1-888-436-2735).

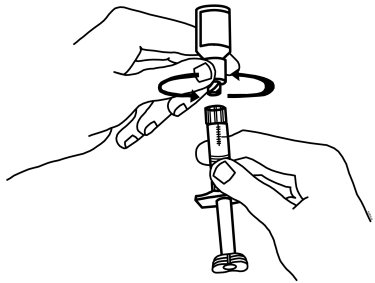
12. Turn the Enbrel vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with your/your child's dose. For adult patients, remove the entire volume (1 mL), unless otherwise instructed by your healthcare provider. Be careful not to pull the plunger completely out of the syringe. Some white foam may remain in the Enbrel vial. This is normal.



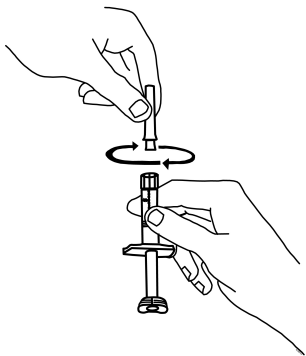
13. Check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to again draw the correct amount of solution back into the syringe.



14. Remove the syringe from the vial adapter, by holding the vial adapter with one hand and turning the syringe counter-clockwise with your other hand. **Do not** touch or bump the plunger. Place the Enbrel vial with the vial adapter on your flat work surface.



15. Continue to hold the barrel of the syringe. With your free-hand, twist the 27-gauge needle onto the tip of the syringe until it fits snugly. **Do not** remove the needle cover from the syringe. Place the syringe on your flat work surface until you are ready to inject Enbrel.

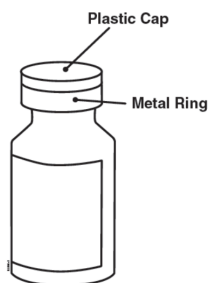


Go to Step 4: Choosing and Preparing an Injection Site.

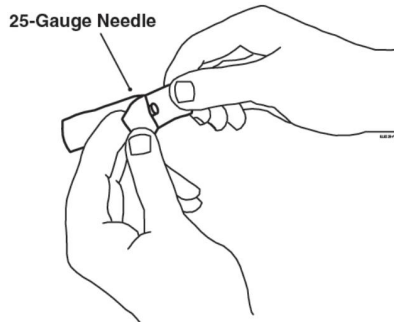
Step 2B: Free-Hand Method

If you are preparing a dose from an Enbrel vial that was previously used, go to Step 3: Preparing Additional Doses from a Single Enbrel Vial.

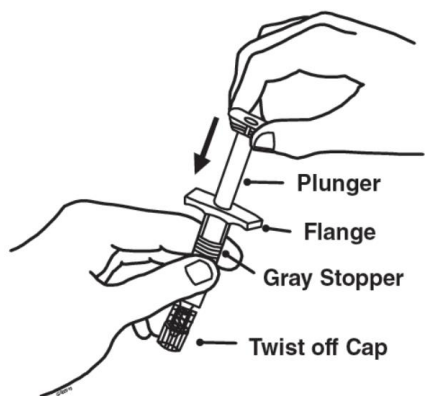
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial. Write the date you mix the powder and solution on the supplied "Mixing Date:" sticker and attach it to the Enbrel vial.



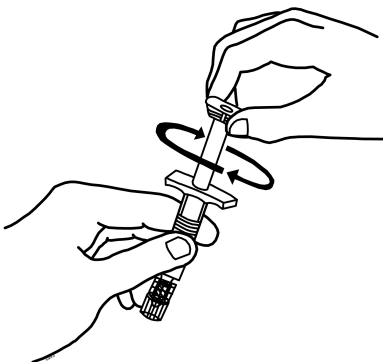
2. Place the Enbrel vial on your flat work surface. Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 25-gauge needle by peeling apart the tabs and set the needle aside for later use. The 25-gauge needle will be used to mix the liquid with the powder and for withdrawing Enbrel from the vial.



4. Slide the plunger into the flange end of the syringe.



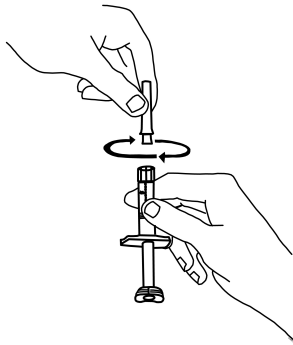
5. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



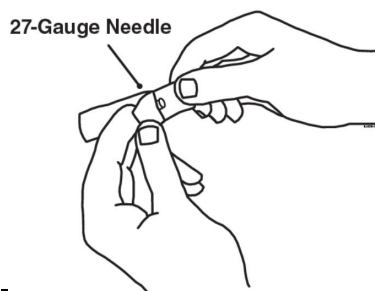
6. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch the syringe tip.



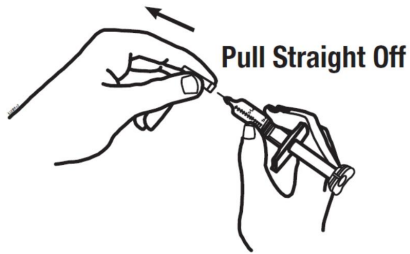
7. Continue to hold the barrel of the syringe. With your free-hand, twist the 25-gauge needle onto the tip of the syringe until it fits snugly. Place the syringe on your flat work surface.



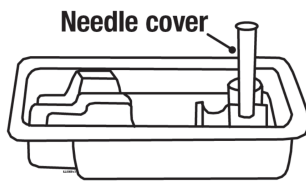
8. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use. The 27-gauge needle will be used to inject the dose.



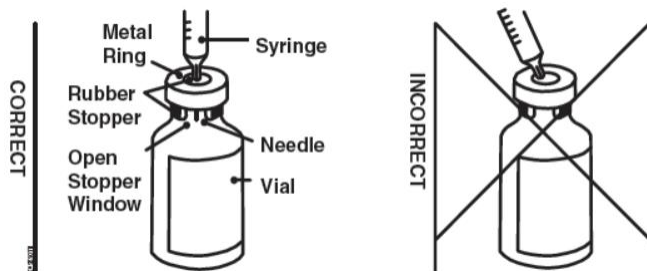
9. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand, and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it. **Do not** touch the needle or allow it to touch any surface. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out.



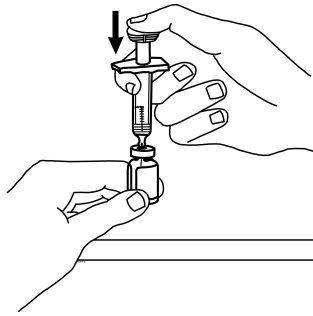
- Place the needle cover (open side up) in the round space marked “N” in the Enbrel dose tray.



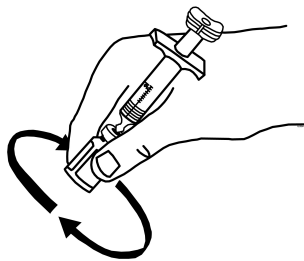
- Place the Enbrel vial on your flat work surface. Hold the syringe with the needle facing up, and gently pull back on the plunger to pull a small amount of air into the syringe. Then, insert the needle straight down through the center ring of the gray stopper (see illustrations). You should feel a slight resistance and then a “pop” as the needle goes through the center of the stopper. Look for the needle tip inside the open stopper window. If the needle is not correctly lined up with the center of the stopper, you will feel constant resistance as it goes through the stopper and no “pop”. The needle may enter at an angle and bend, break or prevent you from adding diluent into the Enbrel vial.



- Push the plunger down very slowly until all liquid from the syringe is in the Enbrel vial. Adding the liquid too fast will cause foaming (bubbles).

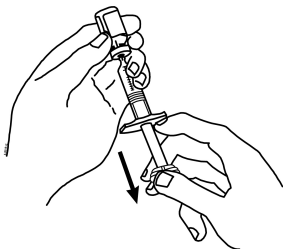


13. Leave the syringe in place. Gently swirl the Enbrel vial in a circular motion to dissolve the powder.

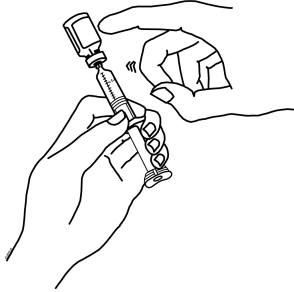


Do not shake. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do not inject the solution if it is discolored, contains lumps, flakes, or particles.** If all the powder in the Enbrel vial is not dissolved or there are particles present after 10 minutes, call 1-888-4ENBREL (1-888-436-2735).

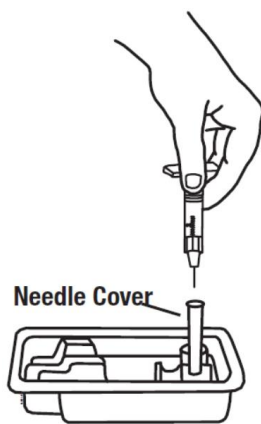
14. With the needle in the Enbrel vial, turn the vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with the correct dose. Make sure to keep the tip of the needle in the solution. Some white foam may remain in the Enbrel vial. This is normal.



15. With the needle still inserted in the Enbrel vial, check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to draw the correct amount of solution back into the syringe.

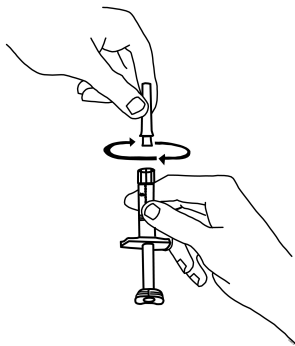


16. Remove the syringe and needle from the Enbrel vial. Keep the needle attached to the syringe and insert the 25-gauge needle straight down into the needle cover in the Enbrel dose tray.



You should hear a “snap” when the needle is secure in the needle cover. Once the needle is secure in the needle cover, untwist the 25-gauge needle from the syringe and dispose of the needle in your sharps disposal container (see “**Step 6: Disposing of Supplies**”).

17. Twist the 27-gauge needle onto the syringe until it fits snugly. **Do not** remove the needle cover from the syringe. Place the syringe on your flat work surface until you are ready to inject Enbrel.



18. If there is enough solution left in the Enbrel vial for another dose, write the date you mixed the powder and liquid in the area marked "Mixing Date:" on the sticker supplied with these instructions, and attach the sticker to the Enbrel vial. Refrigerate the reconstituted (mixed) Enbrel vial (in the dose tray) after mixing. Prepare additional doses from the Enbrel vial as described in Step 3. Otherwise, throw away (discard) the Enbrel vial and any remaining solution.

Go to Step 4: Choosing and Preparing an Injection Site.

Step 3: Preparing Additional Doses from a Single Enbrel Vial

1. Select a clean, well-lit, flat work surface, such as a table.
2. **Do not** reuse the needles and syringes supplied with Enbrel dose tray. You will need new needles and syringes for each additional dose. Your healthcare provider will tell you what type of syringes (1 mL) and needles (25-gauge and 27-gauge) to use. Place the sterile syringe with a 25-gauge needle (for withdrawing Enbrel), a 27-gauge needle (for injecting Enbrel) and two alcohol swabs on your flat work surface.
3. Take the vial of Enbrel solution that is stored in the dose tray out of the refrigerator and place it on your flat work surface.
4. Check the mixing date you wrote on the sticker on the Enbrel vial. **Discard the Enbrel vial if more than 14 days have passed since the Enbrel solution was mixed.**
5. Wash your hands with soap and warm water.
6. Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the stopper with your hands.
7. If the syringe and the 25-gauge needle are not pre-assembled, assemble them as instructed by your healthcare provider.
8. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use. The 27-gauge needle will be used to inject the dose of Enbrel.
9. Hold the syringe and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it. **Do not** touch the needle or allow it to touch any surface. Place the needle cover (open side up) in the round space marked "N" in the Enbrel dose tray.
10. Place the Enbrel vial on your flat work surface. Hold the syringe with the needle facing up, and gently pull back the plunger to pull a small amount of air into the syringe. Then, insert the 25-gauge needle straight down through the center ring of the gray stopper. You should feel a slight resistance and then a "pop" as the needle goes through the center of the stopper. Look for the needle tip inside the open stopper window. If the needle is not

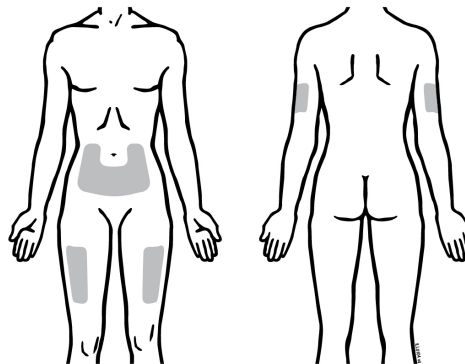
correctly lined up with the center of the stopper, you will feel constant resistance as it goes through the stopper and no “pop”. The needle may enter at an angle and bend, break, or prevent proper withdrawal of Enbrel solution from the vial.

11. Keep the needle in the Enbrel vial and turn the vial upside down. Hold the syringe at eye level, and slowly pull the plunger down to the unit markings on the syringe that correspond to your child’s dose. As the amount of solution in the Enbrel vial drops, you may need to pull the needle back just enough to keep the tip of the needle in the solution.
12. With the needle still inserted in the Enbrel vial, check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the Enbrel vial, slowly pull back on the plunger to again draw the correct amount of solution back into the syringe.
13. Remove the syringe and needle from the Enbrel vial. Keep the needle attached to the syringe and insert the 25-gauge needle straight down into the needle cover in the Enbrel dose tray. You should hear a “snap” when the needle is secure in the needle cover. Once the needle is secure in the needle cover, remove the 25-gauge needle from the syringe and dispose of the needle in a sharps disposal container (see “**Step 6: Disposing of Supplies**”).
14. Attach the 27-gauge needle onto the tip of the syringe until it fits snugly. **Do not** remove the needle cover from the syringe. Place the syringe on your flat work surface until you are ready to inject Enbrel.

Step 4: Choosing and Preparing an Injection Site

1. The 3 recommended injection sites for Enbrel include:
 - the front of the middle thighs
 - the stomach area (abdomen), except for the **2**-inch area right around the navel (belly button)

- the outer area of the upper arms (only if someone else is giving you the injection)



Front

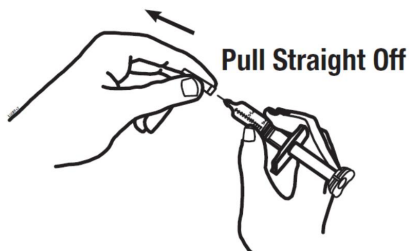
Back

2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area of skin where Enbrel is to be injected, wipe the injection site with a new alcohol swab. **Do not touch this area again before giving the injection.**

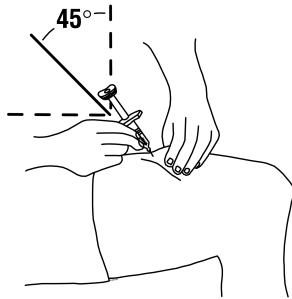
Step 5: Injecting the Enbrel Solution

Do not remove the needle cover from the syringe until you are ready to inject.

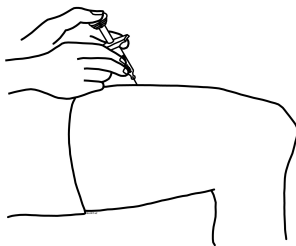
1. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it, and **do not** try to put the needle cover back onto the syringe. When you remove the needle cover, there may be a drop of liquid at the end of the needle. This is normal. **Do not** touch the needle or allow it to touch any surface. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out.



2. With one hand, gently pinch the cleaned area of skin and hold it firmly. With the other hand, hold the syringe (like a pencil) at a 45-degree angle to the skin.



3. With a quick and "dart-like" motion, insert the needle at a 45-degree angle into the skin.
4. When the needle is completely inserted into the skin, let go of the skin that you are holding. With your free-hand, hold the syringe near its base to stabilize it. Then push the plunger to inject all of the Enbrel solution at a slow, steady rate.



5. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted.
6. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds. **Do not** rub the injection site. If needed, you may cover the injection site with a bandage.
7. If your healthcare provider has instructed you to take two Enbrel injections on the same day, repeat the steps to prepare and give an injection of Enbrel. Choose and prepare a new injection site for the second injection.
8. **For the Free-Hand Method:** If there is enough solution left in the Enbrel vial for another dose, refrigerate the reconstituted (mixed) Enbrel vial (in the dose tray) after use. Otherwise, discard the Enbrel vial and any remaining solution.

Step 6: Disposing of Supplies

The syringe, needles, and vial adapter should **never** be reused. **Never** recap a needle.

- Put the used syringes, needles, and vials in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the needles, syringes, and vials 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 syringes and needles. 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 syringe or vial.
- **Do not** recycle the syringe, vial, or sharps disposal container or throw them into household trash.

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

A healthcare provider familiar with Enbrel should answer all questions. Call 1-888-4ENBREL (1-888-436-2735) or visit www.enbrel.com for more information about Enbrel.

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

AMGEN[®]

Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

U.S. License Number 1132

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Revised: 10/2019

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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.

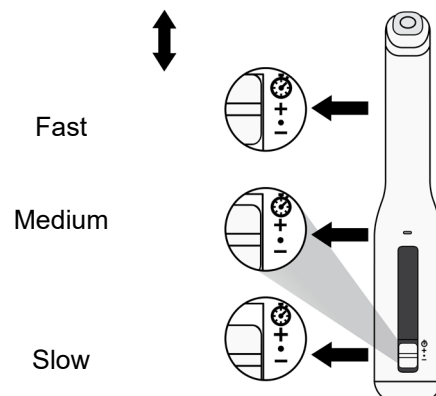
- Three speed settings are available: Fast, Medium, and Slow.
- The factory setting is set to Medium, the black dot (•).

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.

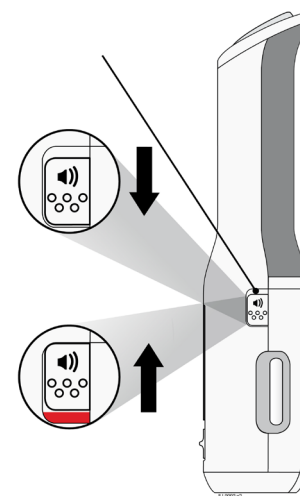
Sound Switch

Sounds on

Slide switch down

Sounds off

Slide switch up (red bar is visible)

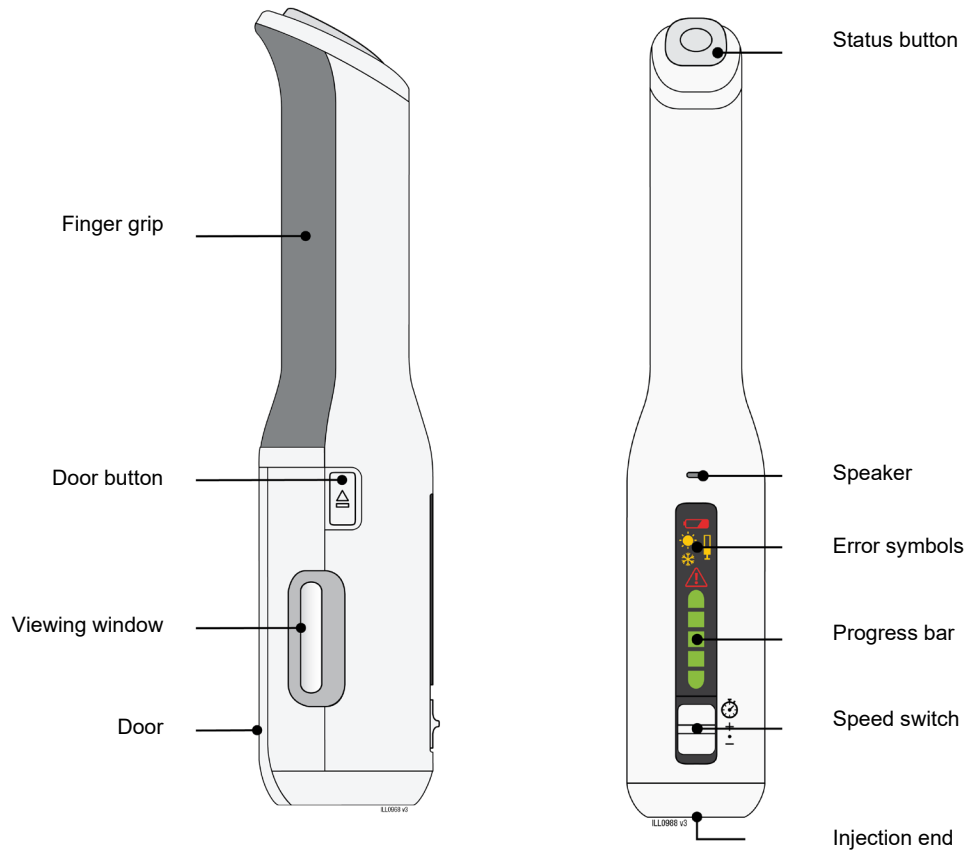


Turn over for step-by-step INSTRUCTIONS FOR USE and other information.

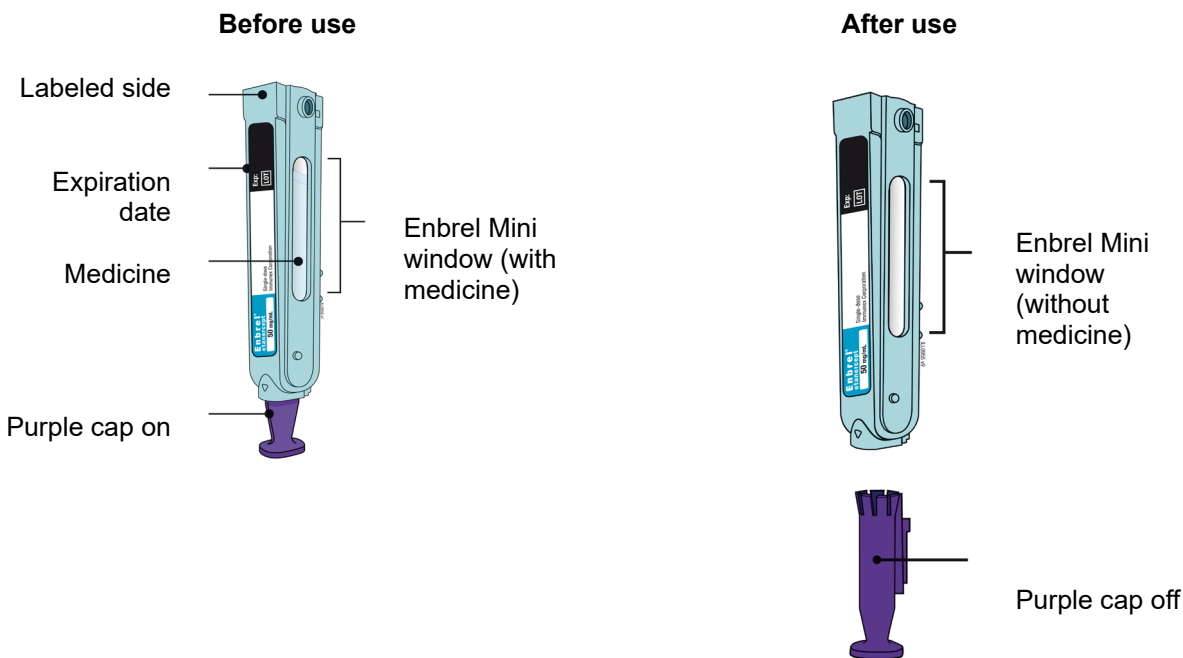
INSTRUCTIONS FOR USE
ENBREL® (en-brel)
(etanercept)
injection, for subcutaneous use
Enbrel Mini® Single-dose Prefilled Cartridge
for use with all AutoTouch® Reusable Autoinjectors

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 needle cover inside the purple cap on the Enbrel Mini cartridge contains 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 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.

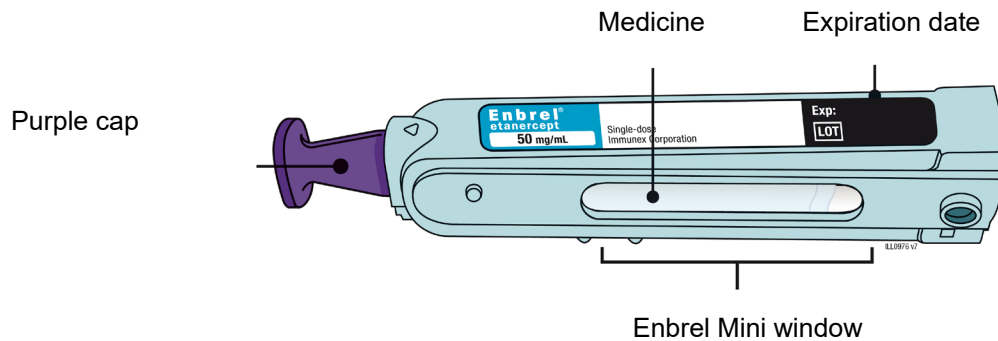
Keep Enbrel Mini and AutoTouch and all medicines out of the reach of children.

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



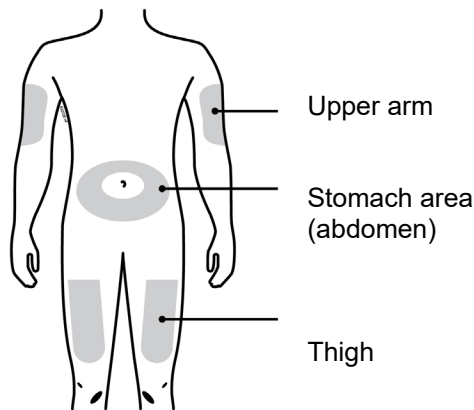
Adhesive bandage



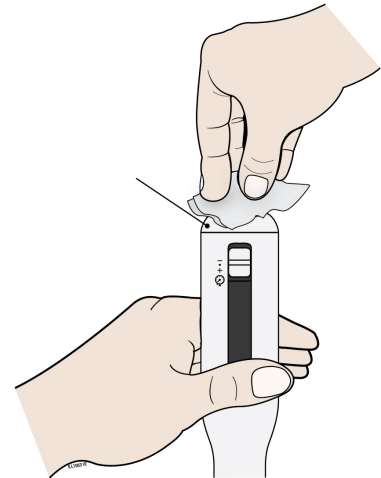
Sharps disposal container

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:

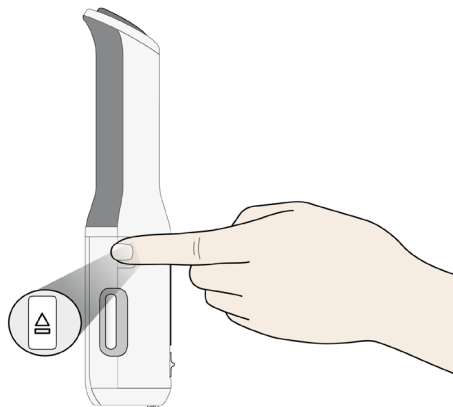
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)

Important:

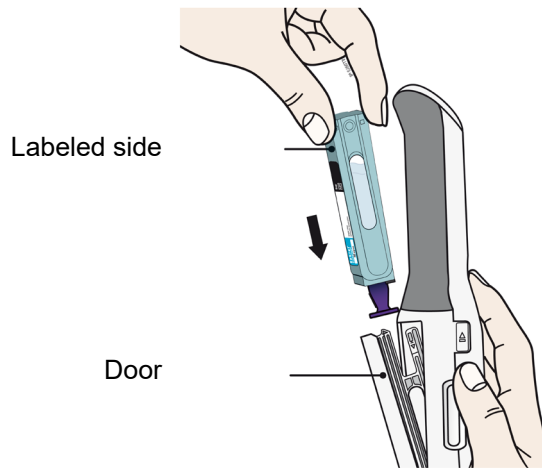
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin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



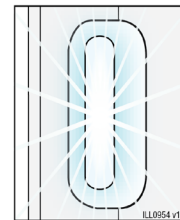
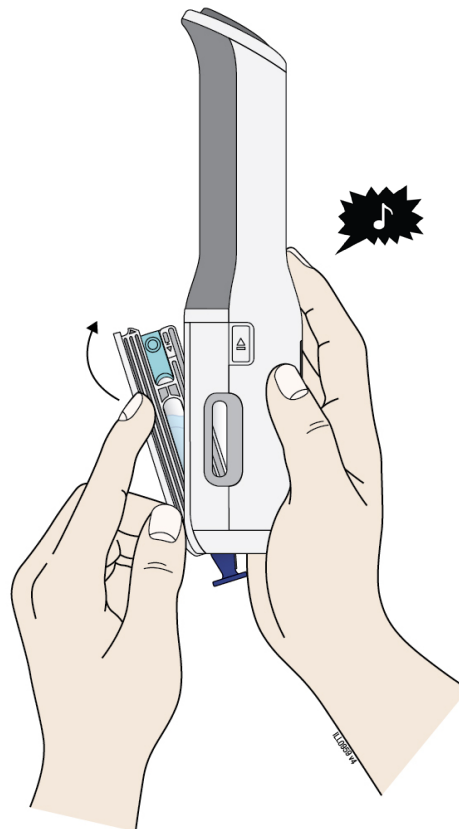
F Hold the Enbrel Mini® single-dose cartridge with the labeled side facing out and slide into door.



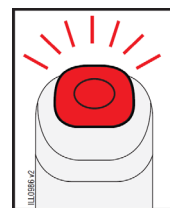
Hold with the labeled side facing out and the purple cap pointing down. Then slide Enbrel Mini into the door. It will slide all the way down into AutoTouch®.

- **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

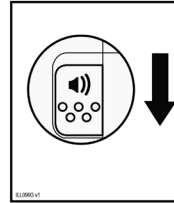


If you see a red
status button call
1-888-4Enbrel
(1-888-436-2735)

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.

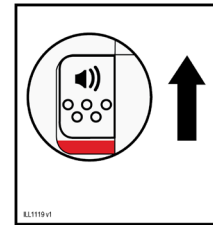
Note: If the sound switch is set to the “sounds off” position, you will not hear this sound. To turn the “sounds on”, slide the sound switch down. The red bar will no longer be visible.

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.

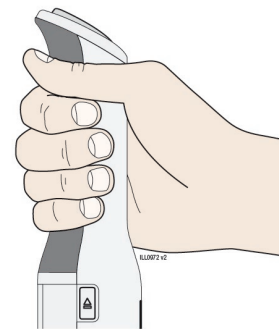
You will now be performing the following tasks in order:

- 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.

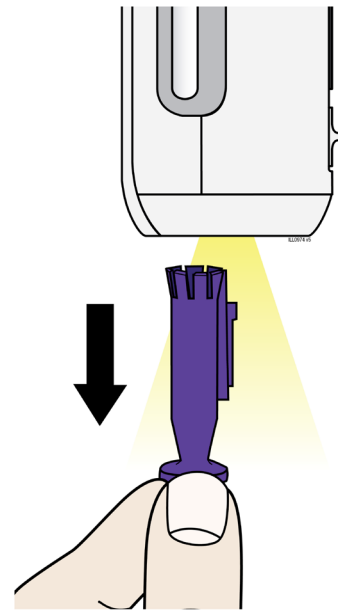
Dispose of the purple cap in a sharps disposal container. Small parts such as the purple cap may cause a choking hazard for children and pets.

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

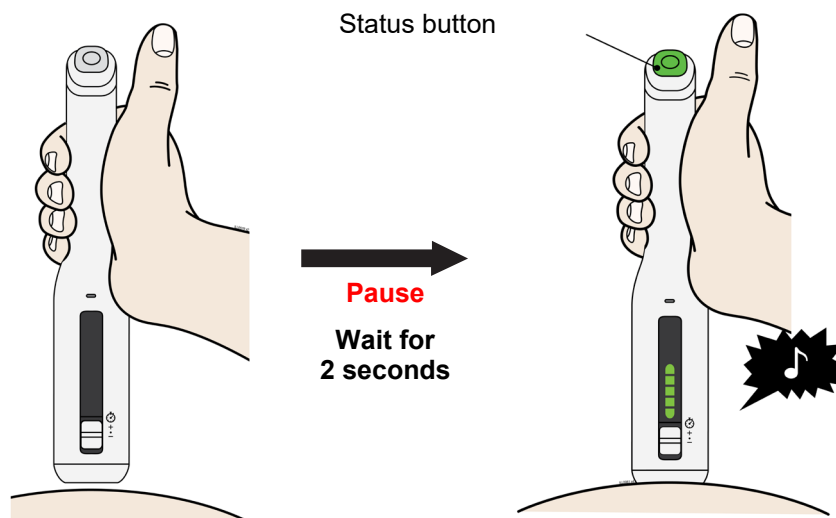
It is normal to see a drop of liquid at the end of Enbrel Mini® needle or bottom of AutoTouch.

- **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.

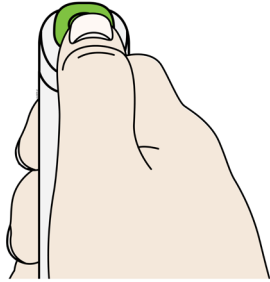


Gently place and hold the AutoTouch® reusable autoinjector on your skin and wait 2 seconds for the status button to turn green. You will hear a “chime” (unless the sound switch is set to the “sounds off” position).

- 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.

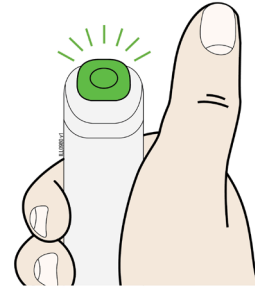
- K Press and release the status button. The status button will start to flash green. You will hear a click when the injection starts.

Press



→
Status button
flashes green

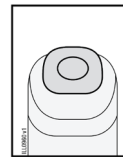
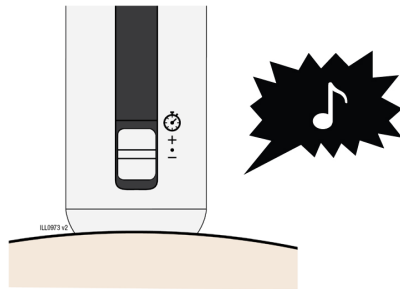
Release



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

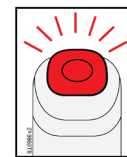
Important: Do not lift AutoTouch® off your skin while the injection is in progress. Continue to hold AutoTouch straight and steady.

- 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



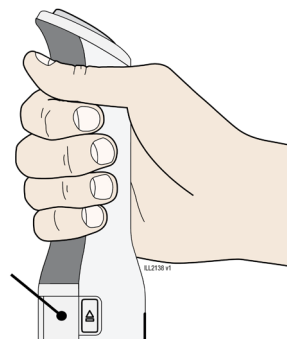
(red light on)

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.

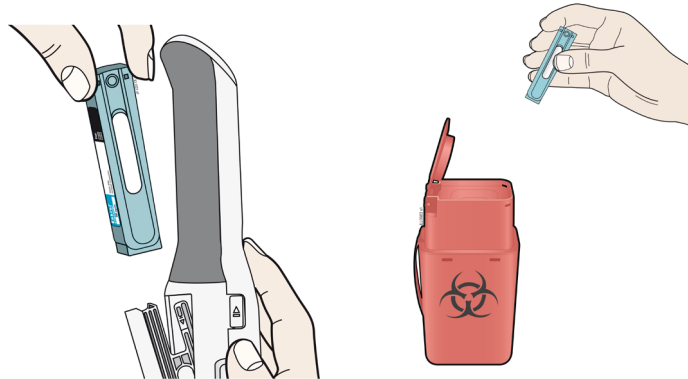
Door



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?



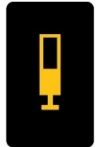
Low battery: The battery is very low. Only a few injections remain. Note: battery icon may be yellow on some devices. Call 1-888-4Enbrel (1-888-436-2735) for a replacement AutoTouch reusable autoinjector.



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:

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