

Instructions for Use

Welcome!

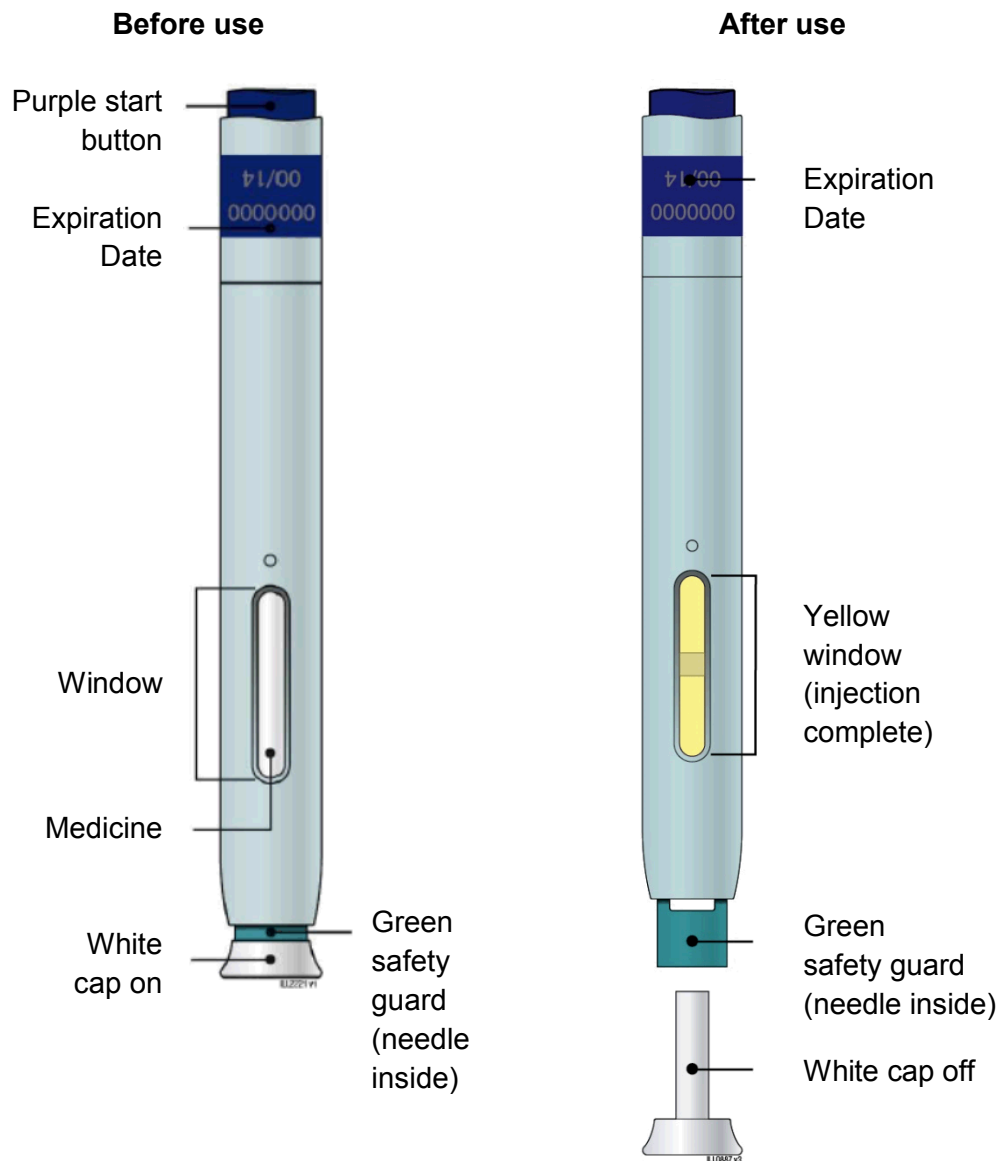
The Enbrel SureClick autoinjector is a single-dose prefilled autoinjector. It contains one 50 mg dose of Enbrel.

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

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

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

Guide to parts



Important: Needle is inside the green safety guard

Important

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

Storing your Enbrel SureClick autoinjectors

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

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

Using your Enbrel SureClick autoinjector

- It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.
- **Do not** use an Enbrel SureClick autoinjector after the expiration date on the label.
- **Do not** shake the Enbrel SureClick autoinjector.
- **Do not** remove the white cap from the Enbrel SureClick autoinjector until you are ready to inject.
- **Do not** use an Enbrel SureClick autoinjector if it has been dropped on a hard surface. Part of the Enbrel SureClick autoinjector may be broken even if you cannot see the break. Use a new Enbrel SureClick autoinjector, and call 1-888-4ENBREL (1-888-436-2735).
- The white needle cap on the Enbrel SureClick autoinjector 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 use the Enbrel SureClick autoinjector. Children who weigh less than 138 pounds should use a different form of Enbrel.**

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

Step 1: Prepare

A Remove one Enbrel SureClick autoinjector from the package.

Carefully lift the autoinjector straight up out of the box.

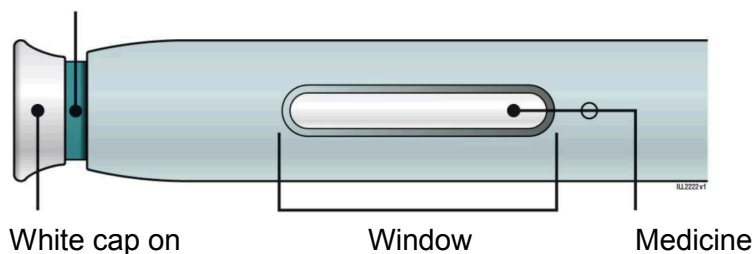
Put the original package with any unused autoinjectors back in the refrigerator.

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

- **Do not** put the autoinjector back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector yet.

B Inspect the Enbrel SureClick autoinjector.

Green safety guard
(needle inside)



Make sure the medicine in the window is clear and colorless.

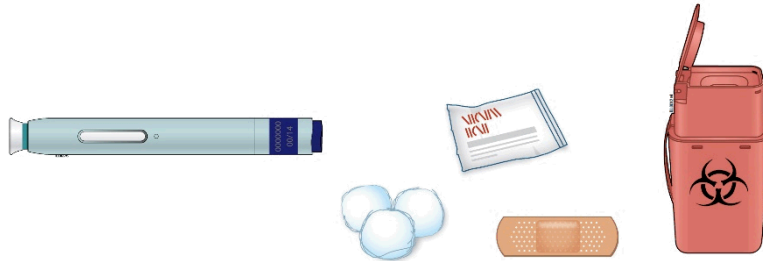
It is okay if you see small white particles in the medicine.

- **Do not** use the autoinjector if:
 - The medicine is cloudy or discolored or contains large lumps, flakes, or colored particles.
 - Any part appears cracked or broken.
 - The white cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

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

C Gather all materials needed for your injection.
Wash your hands thoroughly with soap and water.
On a clean, well-lit work surface, place the:

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



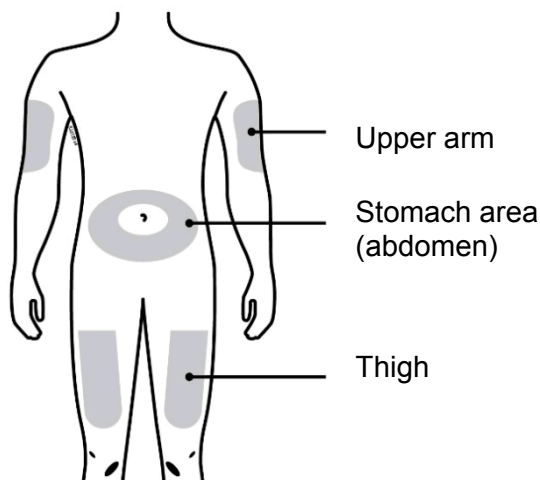
D Prepare and clean your injection site.

Only use these injection sites:

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

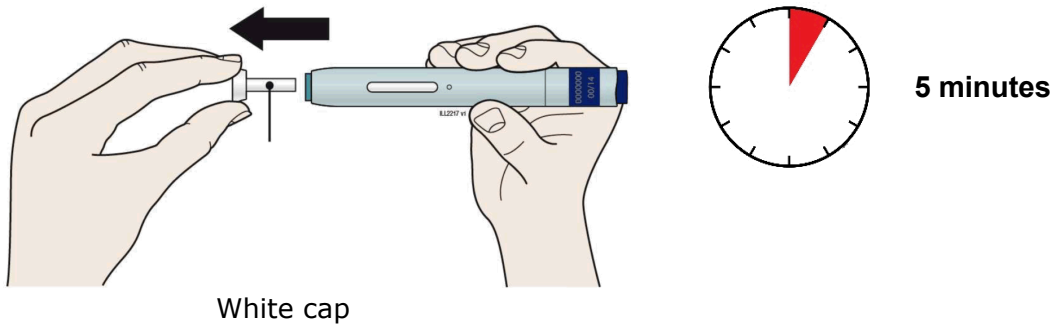
Clean your injection site with an alcohol wipe. Let your skin dry.

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



Step 2: Get ready

E Pull white cap straight off, only when you are ready to inject. **Do not** leave the white cap off for more than **five minutes**. This can dry out the medicine.

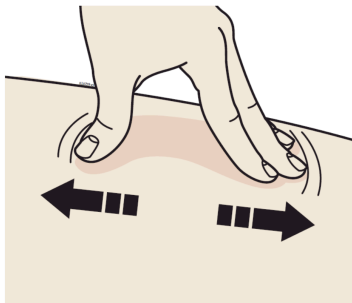


It is normal to see a drop of liquid at the end of the needle or green safety guard.

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

F 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.

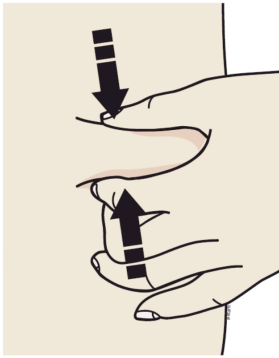
Stretch method



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

OR

Pinch method

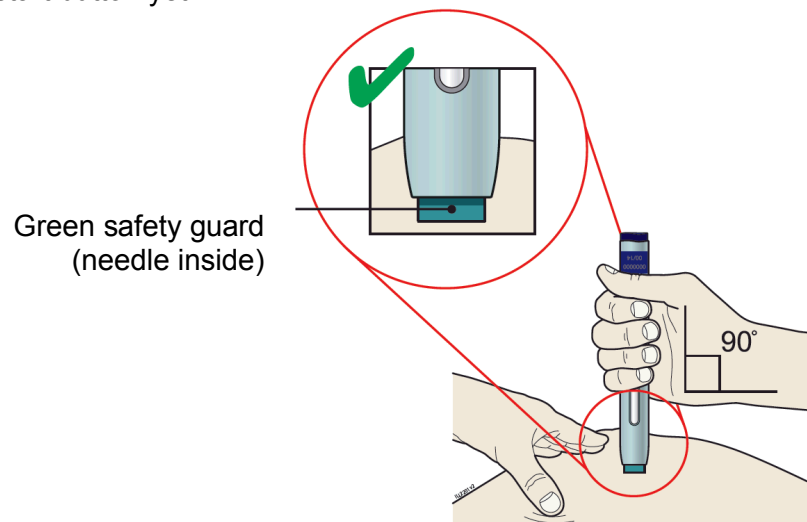


Pinch skin firmly between your thumb and fingers, creating an area about **two** inches wide.

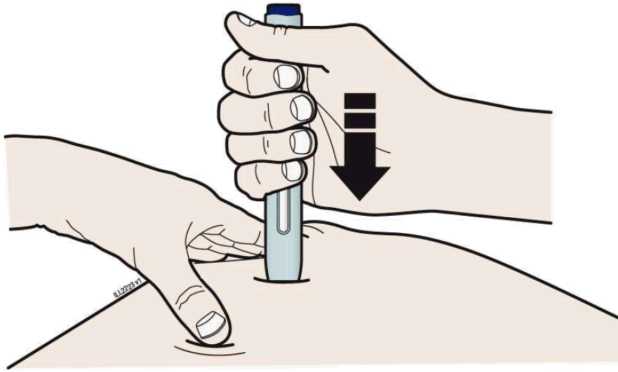
Important: Keep the skin stretched or pinched while injecting.

Step 3: Inject

G 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.



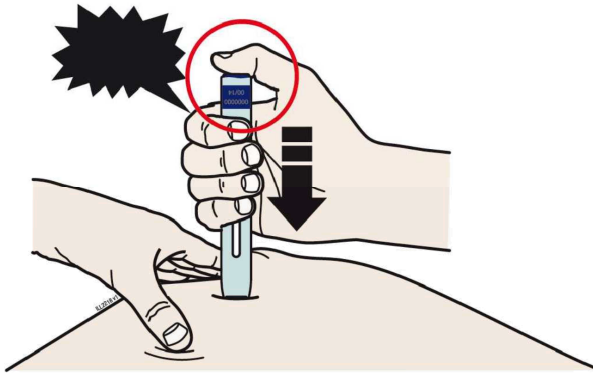
H Firmly **push** the autoinjector down onto skin until it stops moving.



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

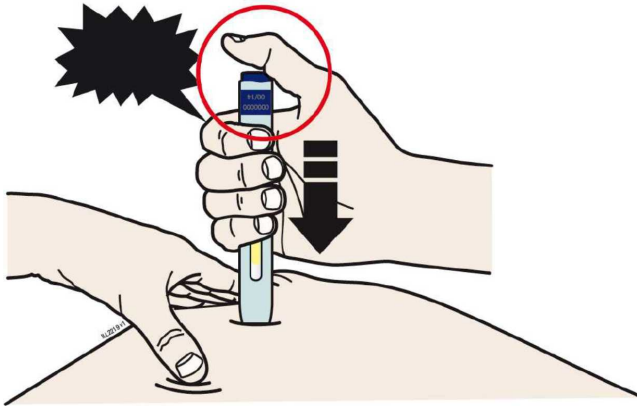
I When you are ready to inject, **press** the purple start button.

“click”

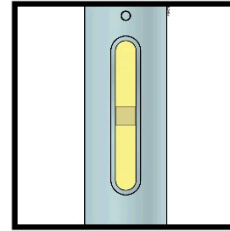


J Keep **pushing** down on your skin. Then lift your thumb while still holding the autoinjector on your skin. Your injection could take about **15 seconds**.

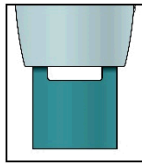
"click"



15 seconds



Window turns from clear to yellow when the injection is done. You may hear a second click.

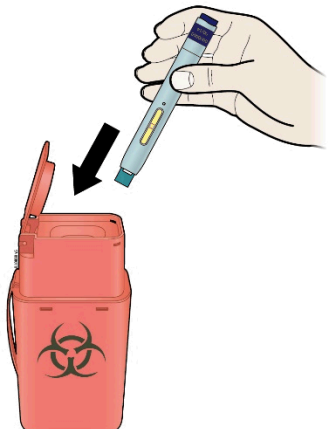


Note: After you remove the autoinjector from your skin, the needle will be automatically covered.

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

K Discard the used autoinjector and the white cap.



- Put the used SureClick autoinjector in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the SureClick autoinjector in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **Do not** reuse the autoinjector.
- **Do not** recycle the autoinjector or sharps disposal container or throw them into household trash.

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

L Examine the injection site.

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

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

Commonly asked questions

What will happen if I press the purple start button before I am ready to do the injection on my skin?

Even when you press the purple start button, the injection will only happen when the green safety guard is also pushed into the autoinjector.

Can I move the autoinjector around on my skin while I am choosing an injection site?

It is okay to move the autoinjector around on the injection site as long as you **do not** press the purple start button. However, if you press the purple start button and the green safety guard is pushed into the autoinjector, the injection will begin.

Can I release the purple start button after I start my injection?

You can release the purple start button, but continue to hold the autoinjector firmly against your skin during the injection.

Will the purple start button pop up after I release my thumb?

The purple start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

What do I do if I did not hear a click after pushing the device down on my skin for 15 seconds?

If you did not hear a click, you can confirm a complete injection by checking that the window has turned yellow.

Whom do I contact if I need help with the autoinjector or my injection?

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

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



Manufactured by:

Immunex Corporation
Thousand Oaks, CA 91320-1799
U.S. License Number 1132

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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.

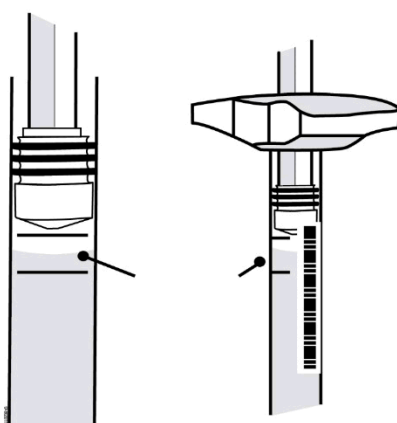
Storage of your Enbrel prefilled syringe

- 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 14 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 14 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.

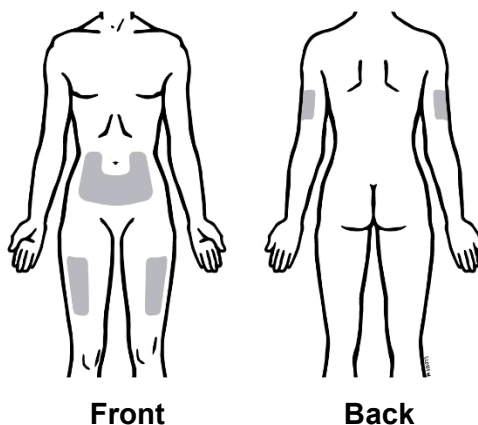


Fill Level Indicator

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)

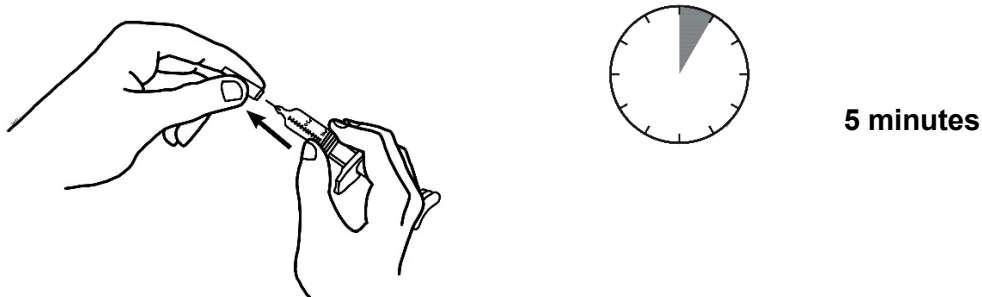


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area 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.

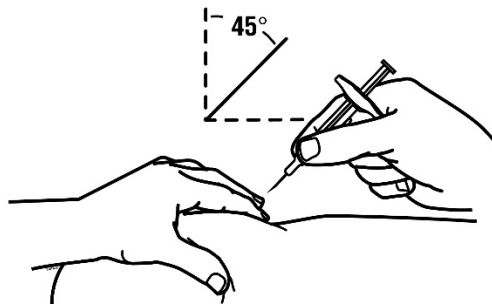
1. Pick up the prefilled syringe from your flat work surface. Hold the barrel of the prefilled syringe with one hand and pull the needle cover straight off, only when you are ready to inject. **Do not** leave the needle cover off for more than **five minutes**. This can dry out the medicine.



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.



Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

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Revised: 10/2019



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**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.**

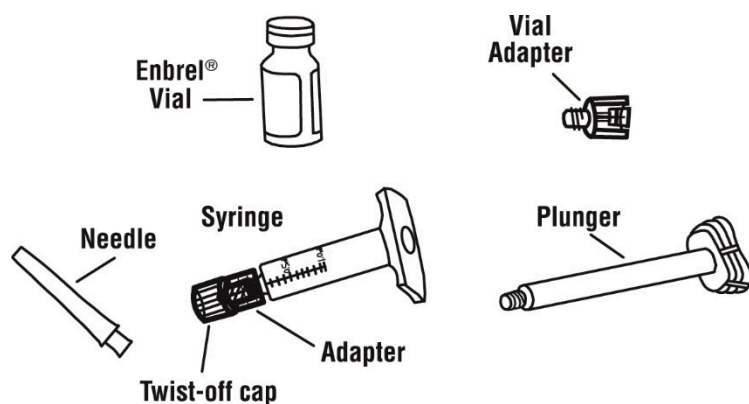
If you have any questions about storage, contact your healthcare provider or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

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.**

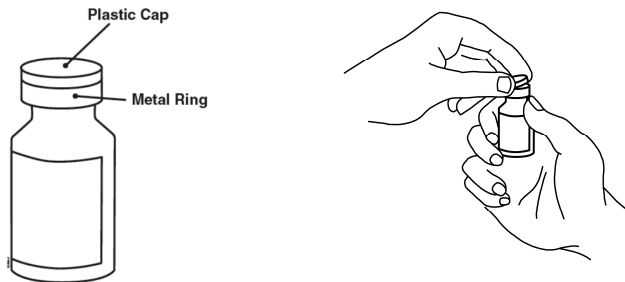
If you are using the vial of Enbrel for more than one dose, you should write the date you mixed the powder and liquid in the area marked "Mixing Date:" on the sticker supplied with these instructions, and attach the sticker to the Enbrel vial.

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.

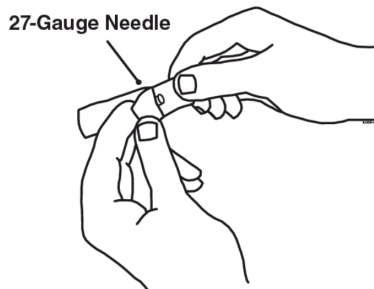
The Enbrel solution must be used within 14 days of the mixing date. You should discard the Enbrel vial and any remaining solution if it is not used within 14 days. **Do not** mix any remaining liquid in one vial of Enbrel solution with another.

STEP 2A: Vial Adapter Method

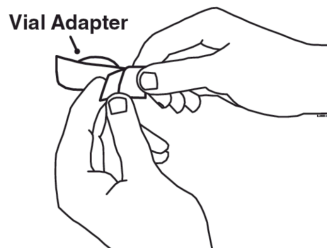
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial.



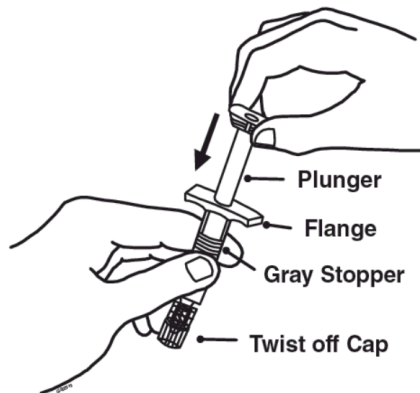
2. Place the Enbrel vial on your flat work surface or turn your dose tray upside down and place your Enbrel vial in the round space marked "V". Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 27-gauge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



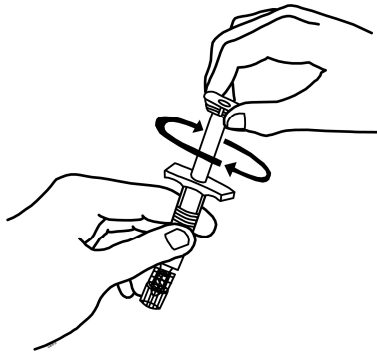
4. Open the wrapper that contains the vial adapter by peeling apart the tabs and set the vial adapter aside for later use. **Do not** touch the vial adapter's twist-on end or the spike inside.



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



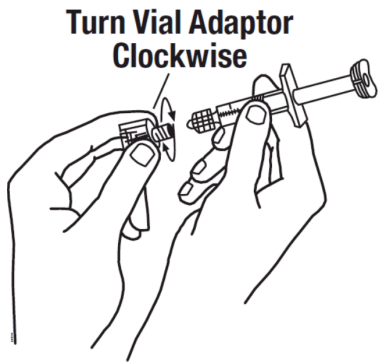
6. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



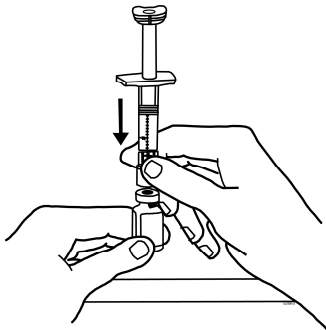
7. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch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



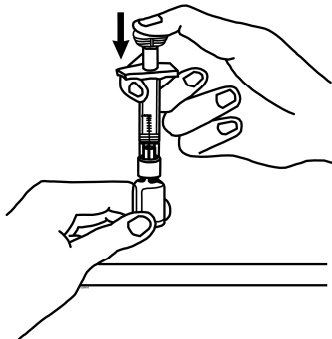
8. Once the twist-off cap is removed, pick up the vial adapter with your free-hand. Twist the vial adapter onto the syringe, turning clockwise until you feel a slight resistance. **Do not over-tighten.**



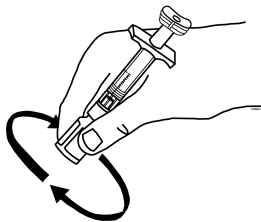
9. Hold the Enbrel vial upright on your flat work surface. Grasp the sides of the vial adapter and place it over the top of the Enbrel vial. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. Insert the vial adapter into the gray stopper on the Enbrel vial. The plastic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

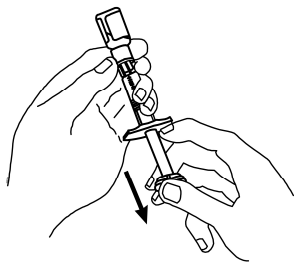


11. Gently swirl the Enbrel vial in a circular motion to dissolve the powder. If you used the dose tray to hold your Enbrel vial, take the vial (with the vial adapter and syringe still attached) out of the dose tray, and gently swirl the vial in a circular motion to dissolve the powder.

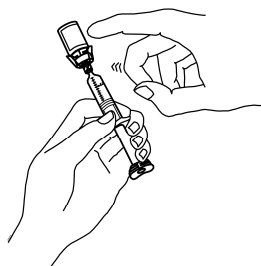


Do not shake. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do not inject the solution if it is discolored, contains lumps, flakes, or particles.** 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).

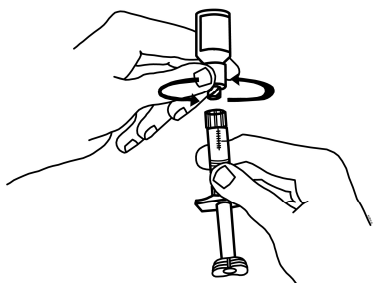
12. Turn the Enbrel vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with your/your child's dose. For adult patients, remove the entire volume (1 mL), unless otherwise instructed by your healthcare provider.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



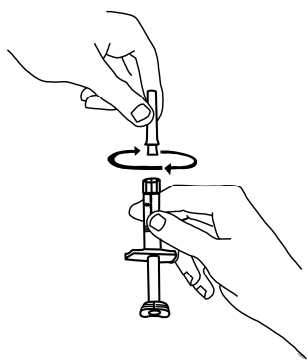
13. Check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to again draw the correct amount of solution back into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

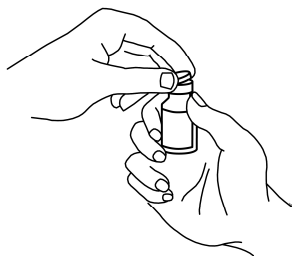
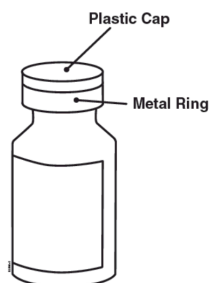


Go to Step 4: Choosing and Preparing an Injection Site.

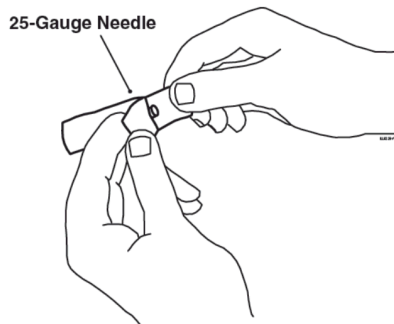
Step 2B: Free-Hand Method

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.

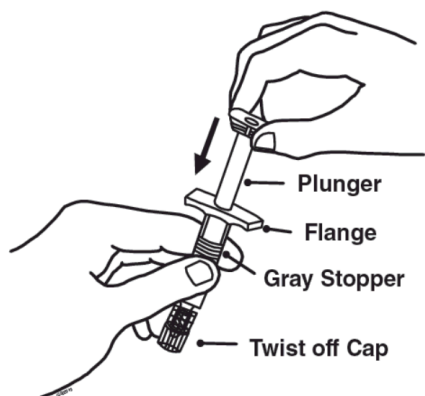
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial. Write the date you mix the powder and solution on the supplied "Mixing Date:" sticker and attach it to the Enbrel vial.



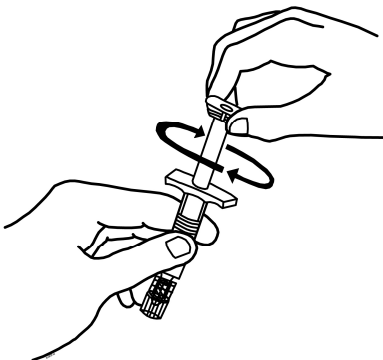
2. Place the Enbrel vial on your flat work surface. Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 25-gauge needle by peeling apart the tabs and set the needle aside for later use. The 25-gauge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



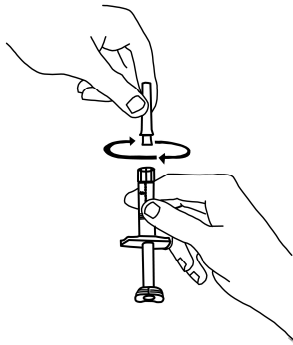
5. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



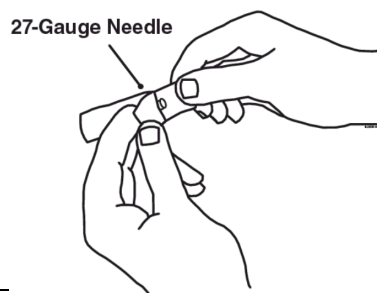
6. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch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



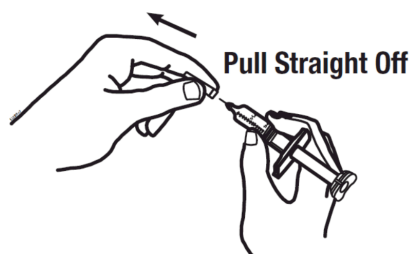
7. Continue to hold the barrel of the syringe. With your free-hand, twist the 25-gauge needle onto the tip of the syringe until it fits snugly. Place the syringe on your flat work surface.



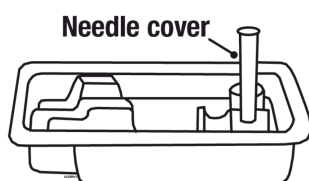
8. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use. The 27-gauge needle will be used to inject the dose.



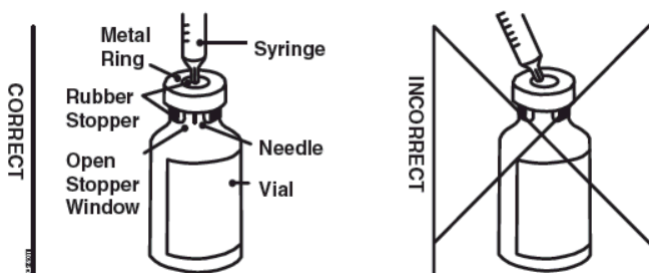
9. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand, and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it. **Do not** touch the needle or allow it to touch any surface. **Do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



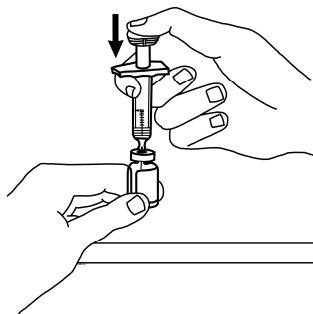
10. Place the needle cover (open side up) in the round space marked “N” in the Enbrel dose tray.



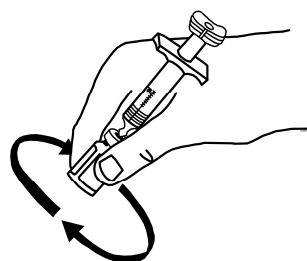
11. Place the Enbrel vial on your flat work surface. Hold the syringe with the needle facing up, and gently pull back on the plunger to pull a small amount of air into the syringe. Then, insert the needle straight down through the center ring of the gray stopper (see illustrations). You should feel a 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.



12. 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).

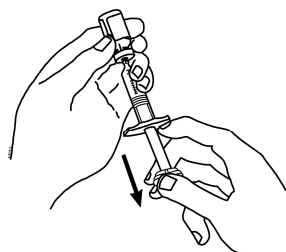


13. Leave the syringe in place. Gently swirl the Enbrel vial in a circular motion to dissolve the powder.

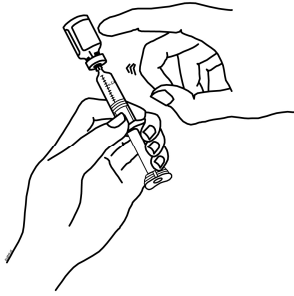


Do not shake. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do not inject the solution if it is discolored, contains lumps, flakes, or particles.** 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).

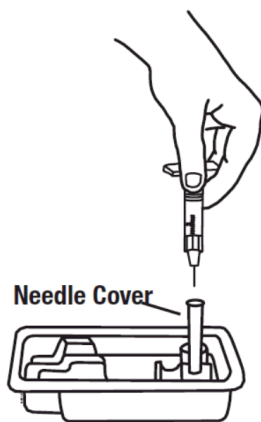
14. With the needle in the Enbrel vial, turn the vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with the correct dose. Make sure to keep the tip of the needle in the solution. Some white foam may remain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

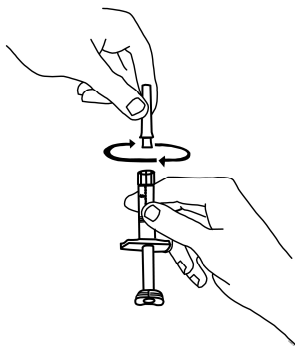


16. Remove the syringe and needle from the Enbrel vial. Keep the needle attached to the syringe and insert the 25-gauge needle straight down into the needle cover in the Enbrel dose tray.



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

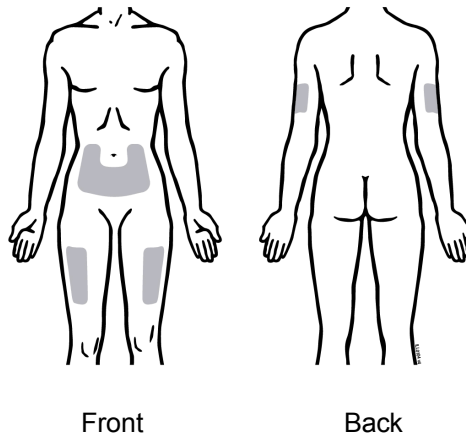
correctly lined up with the center of the stopper, you will feel constant resistance as it goes through the stopper and no “pop”. The needle may enter at an angle and bend, break, or prevent proper withdrawal of Enbrel solution from the vial.

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)

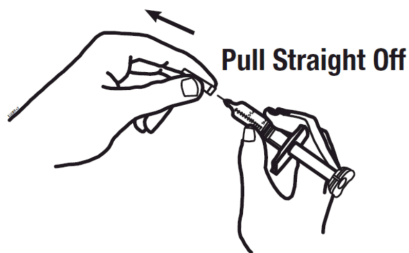


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area 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.**

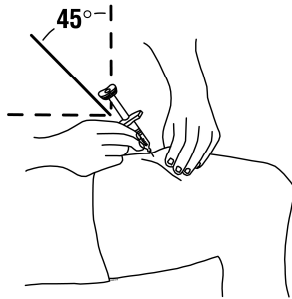
Step 5: Injecting the Enbrel Solution

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

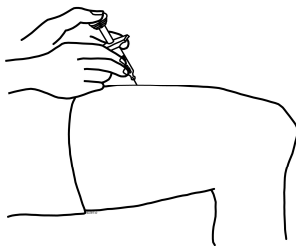
1. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it, and **do not** try to put the needle cover back onto the syringe. 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



This printed material is recyclable.

Front Panel Text

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

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 with Enbrel Mini® single-dose prefilled cartridge for use with Enbrel® (etanercept).

Speed switch

Changing injection speed

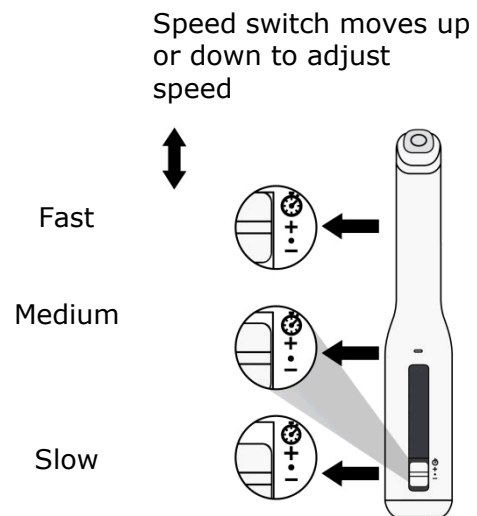
The AutoTouch reusable autoinjector allows you to choose the speed of your injection. You can try the three speeds to decide which speed is most comfortable for you.

- Three speed settings are available: Fast, Medium, and Slow.
- The AutoTouch 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 AutoTouch on your skin and press the start button. The injection speed cannot be changed after you begin an injection.



Sound switch

Turning sounds off

AutoTouch makes sounds (🎵) to help guide your injection. When you receive a new AutoTouch, 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

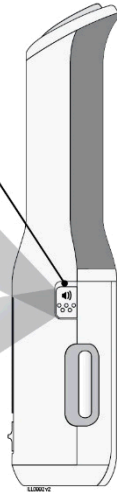
Sounds on

Slide switch down



Sounds off

Slide switch up
(red bar is visible)

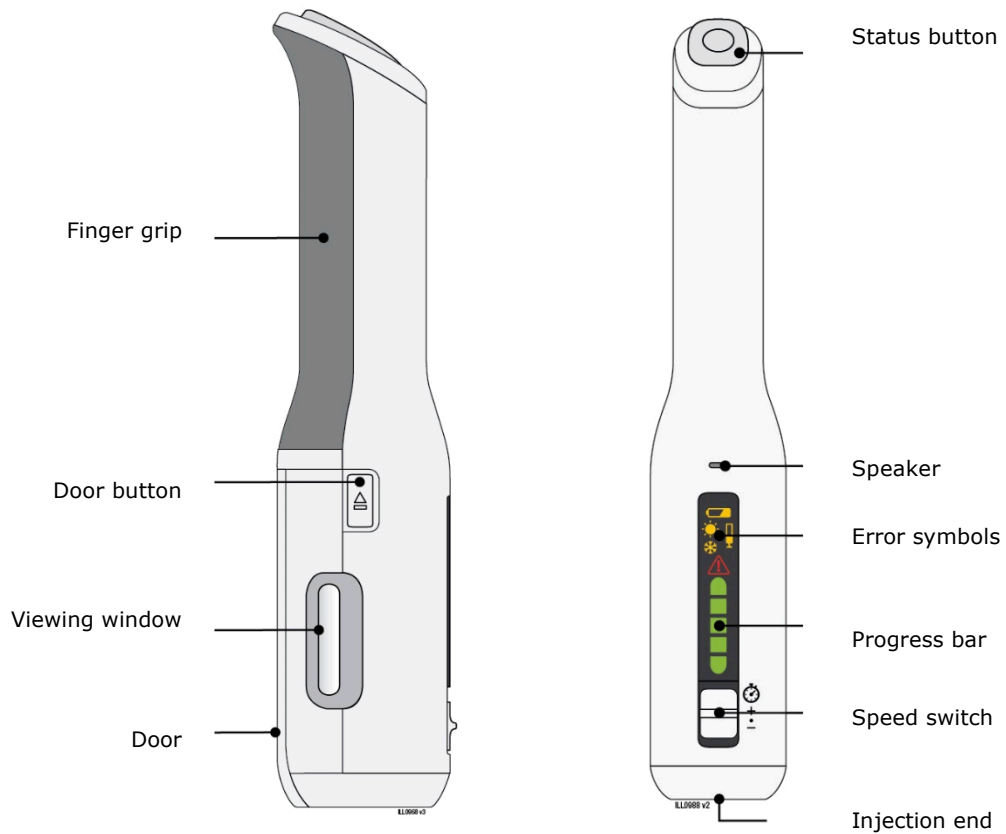


Turn over for step-by-step INSTRUCTIONS FOR USE and other information.

INSTRUCTIONS FOR USE
Enbrel® (en-brel) (etanercept)
injection, for subcutaneous use
Enbrel Mini® Single-Dose Cartridge
for use with AutoTouch® Reusable Autoinjector

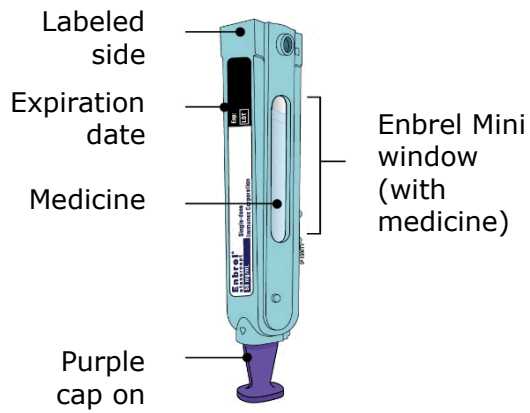
Guide to parts

AutoTouch® reusable autoinjector

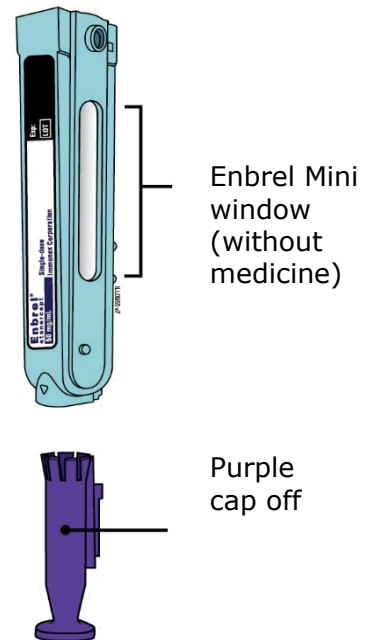


Enbrel Mini[®] single-dose cartridge

Before use



After use



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 14 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 14 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.²
- **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 use Enbrel Mini. Children who weigh less than 138 pounds should use 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.

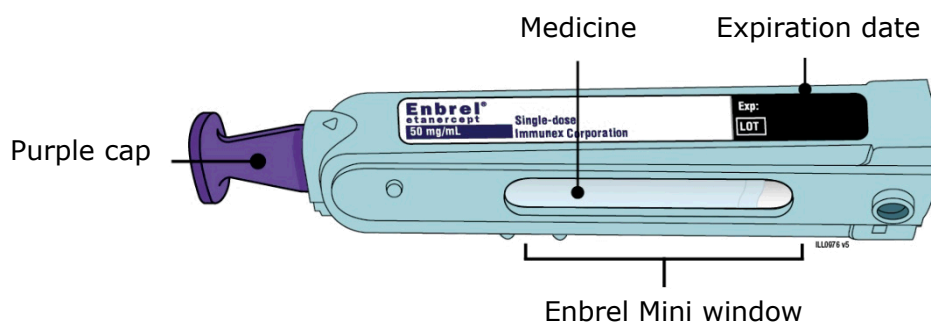
For more information or help, visit www.enbrel.com or call 1-888-4Enbrel (1-888-436-2735). Read your AutoTouch User Manual for additional care and storage information.

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 or 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.

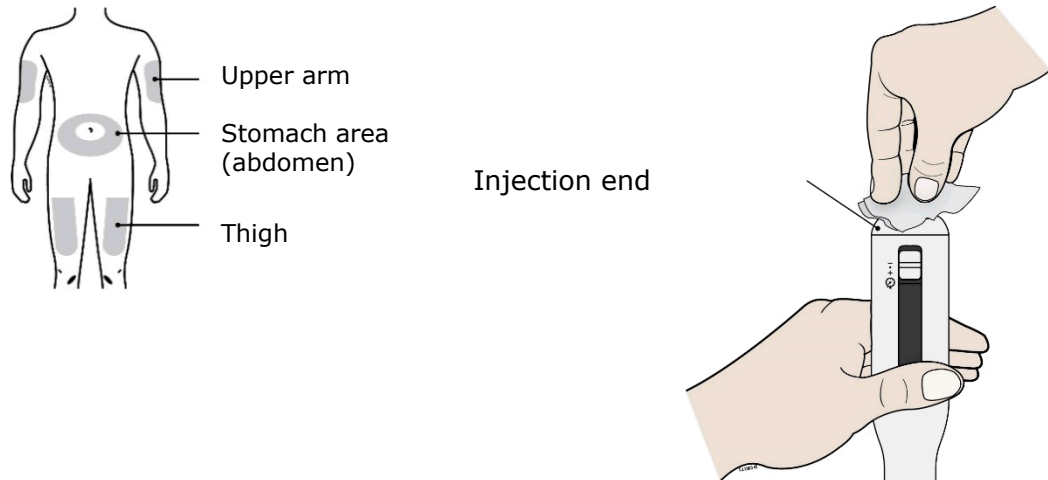
Place the following on a clean, well-lit, flat surface:

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



D Prepare and clean your injection site.

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



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

You can use:

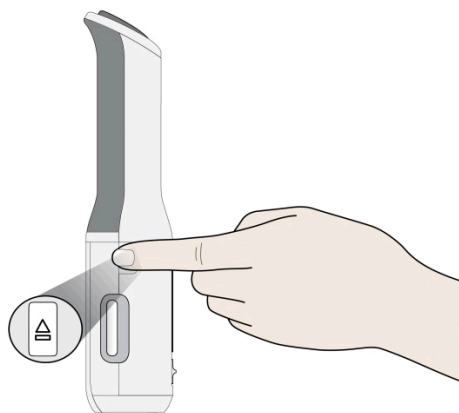
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)

Important:

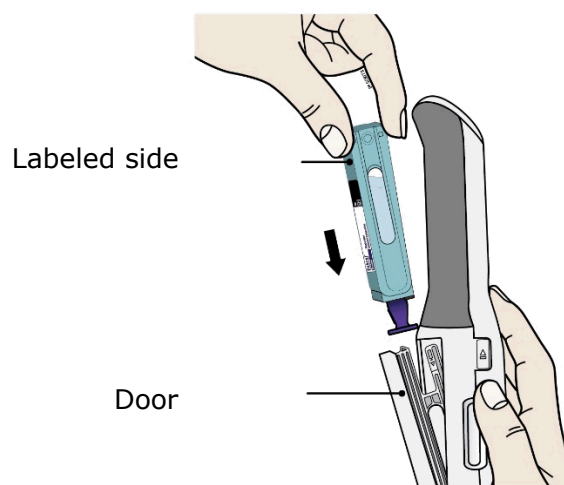
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin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



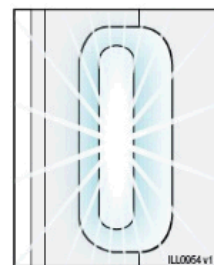
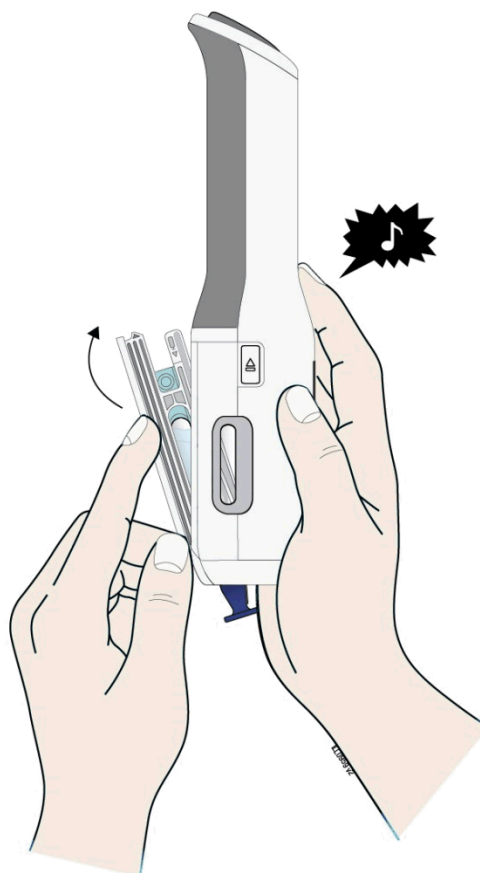
F Hold the Enbrel Mini[®] single-dose cartridge with the labeled side facing out and slide into door.



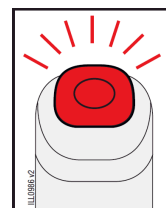
Hold with the labeled side facing out and the purple cap pointing down. Then slide Enbrel Mini into the door. It will slide all the way down into AutoTouch[®].

- **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

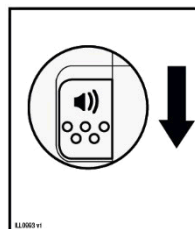


If you see a red status button call 1-888-4Enbrel (1-888-436-2735)

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.

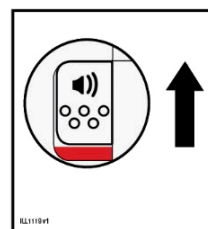
Note: If the sound switch is set to the “sounds off” position, you will not hear this sound. To turn the “sounds on”, slide the sound switch down. The red bar will no longer be visible.

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.

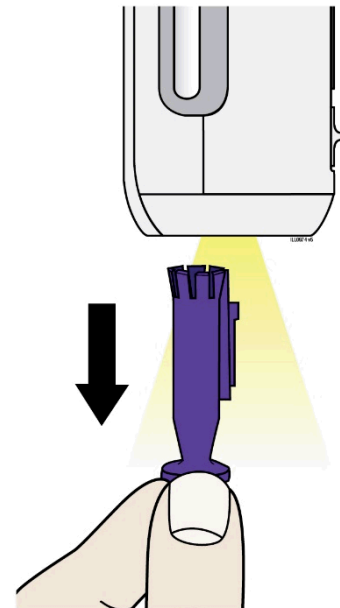
Dispose of the purple cap in a sharps disposal container. Small parts such as the purple cap may cause a choking hazard for children and pets.

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

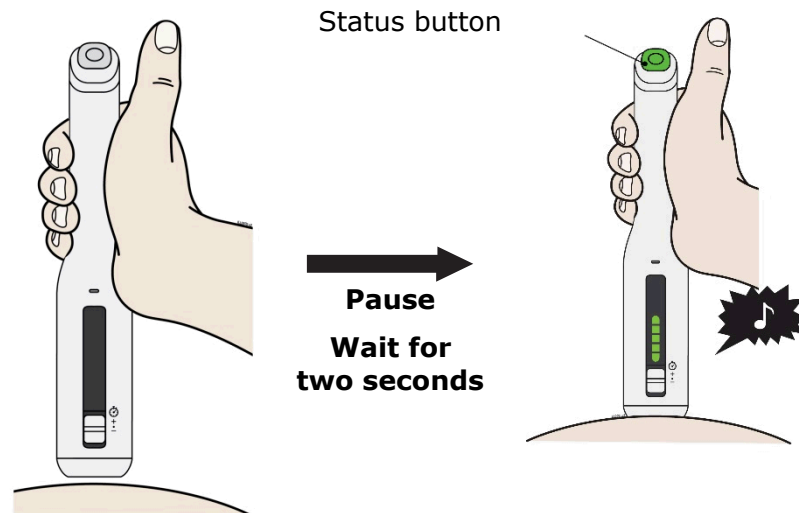
It is normal to see a drop of liquid at the end of Enbrel Mini® needle or bottom of AutoTouch.

- **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.



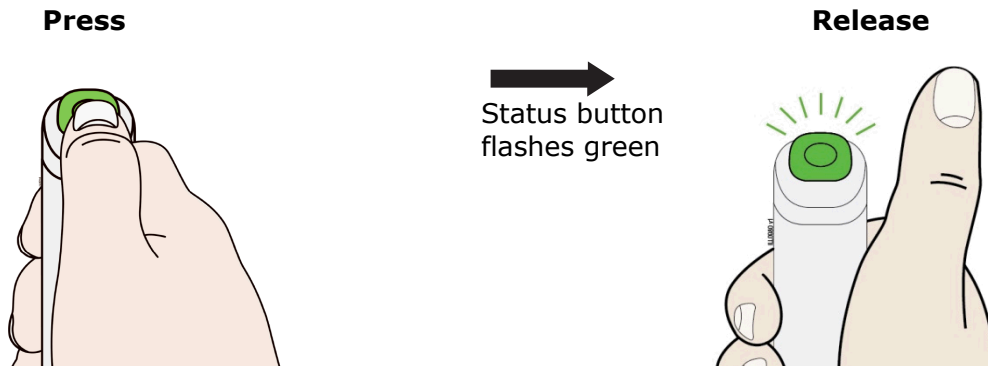
- J** Place and hold on the skin. Wait for the status button to turn green and a chime to sound.



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.

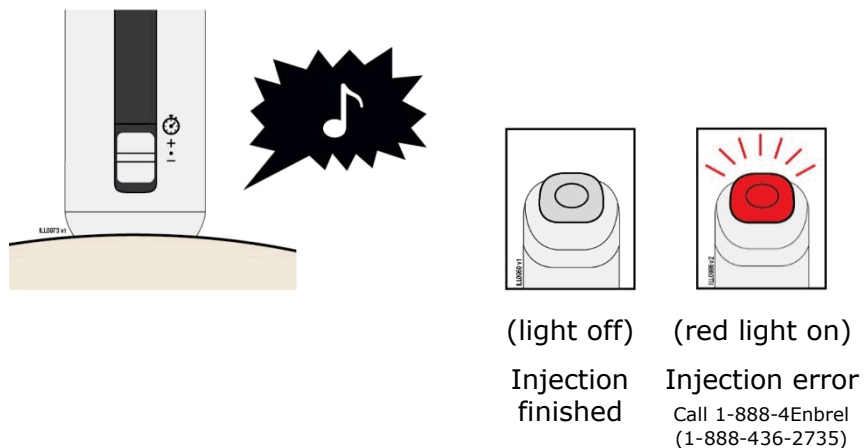
- K** Press and release the status button. The status button will start to flash green. You will hear a click when the injection starts.



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.



Lift AutoTouch® off your skin.

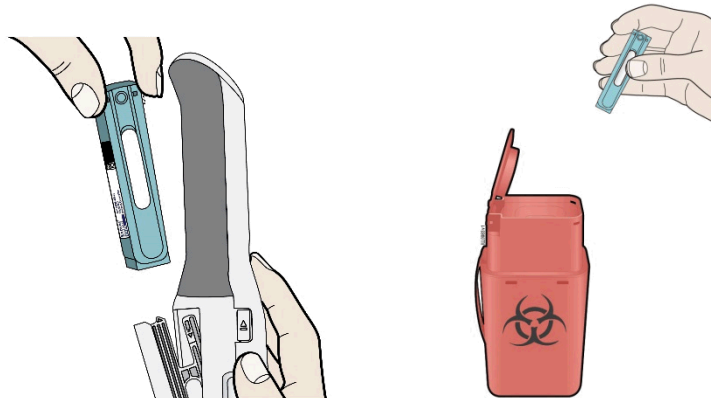
When your injection is finished, you will hear a motor noise for a few seconds. When finished, the door will automatically open. Do not block the door with your hand.



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 a 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 a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright and stable during use
- leak-resistant, and properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>

- **Do not** reuse 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 AutoTouch 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. Call 1-888-4Enbrel (1-888-436-2735) for a replacement AutoTouch reusable autoinjector.



Battery dead: The battery is dead. Call 1-888-4Enbrel (1-888-436-2735) for a replacement AutoTouch reusable autoinjector.



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



AMGEN®

Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

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[partnumber]

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