

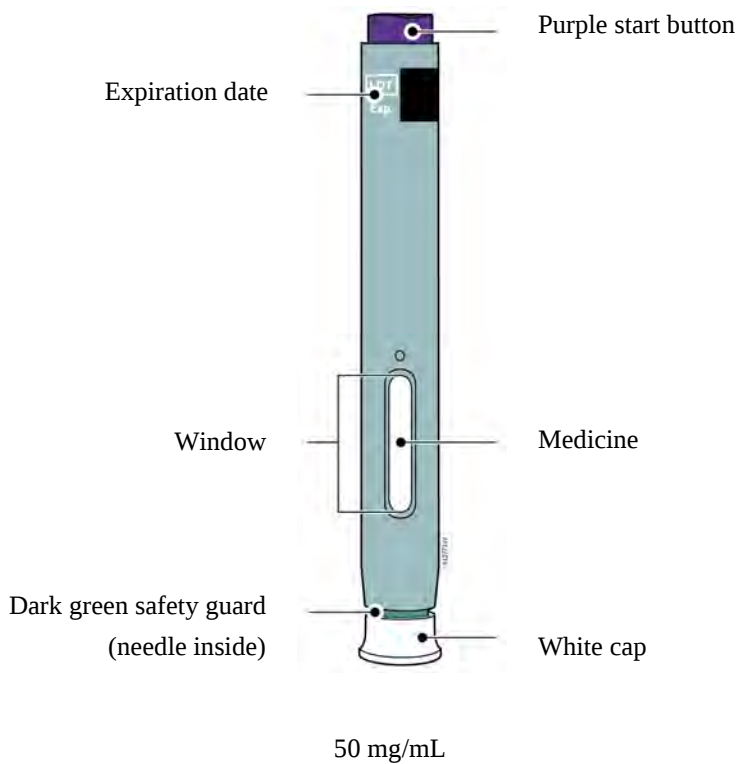
INSTRUCTIONS FOR USE
ENBREL® [en-brel]
(etanercept)
injection, for subcutaneous use
50 mg/mL
single-dose prefilled SureClick® autoinjector

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

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

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

Getting to know the prefilled autoinjector



Important Information You Need to Know Before Injecting ENBREL

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- Check the autoinjector label and prescription to make sure you have the correct medicine and dose.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.
- **Do not** use the autoinjector if it has been frozen.

- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-888-4ENBREL (1-888-436-2735).
- **Children must weigh at least 138 pounds to use the ENBREL SureClick autoinjector. Children who weigh less than 138 pounds should use a different form of ENBREL.**
- The autoinjector is not made with natural rubber latex.

Frequently asked questions:

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

Where to get help:

If you want more information or help using ENBREL:

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

Storing and Preparing to Inject ENBREL



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

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

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



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

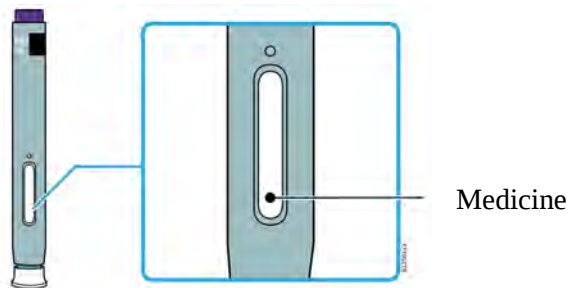
- Remove the autoinjector and put any unused autoinjectors back into the refrigerator.
 - Let the autoinjector warm up naturally.
 - **Do not** heat the autoinjector with hot water, a microwave, or direct sunlight.
 - **Do not** shake the autoinjector at any time.
 - Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.
-



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

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

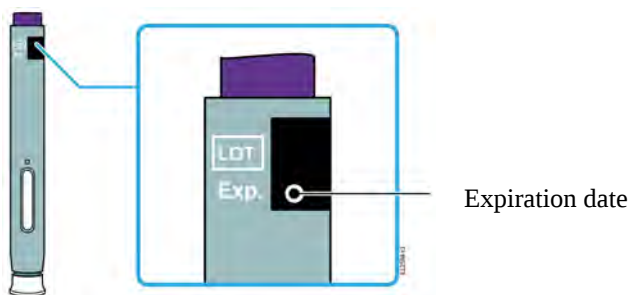
Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within **30** days.



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

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

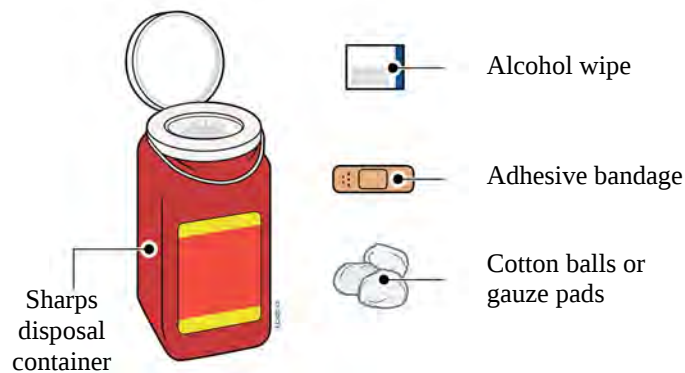
Important: If the medicine is cloudy, discolored, or contains large lumps, flakes or colored particles, or if the autoinjector is damaged or expired, call 1-888-4ENBREL (1-888-436-2735).



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

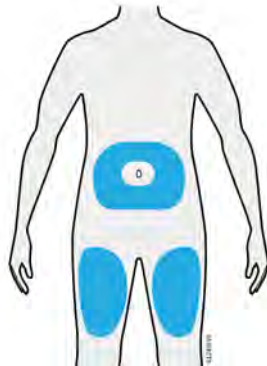
- **Do not** use the autoinjector if the expiration date has passed.
- **Do not** use the autoinjector if:
 - the white cap is missing or loose in carton,
 - it has cracks or broken parts, or
 - it has been dropped on a hard surface.

Getting Ready to Inject ENBREL



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

- ENBREL autoinjector (room temperature),
- Sharps disposal container [see Completing the Injection and Disposal],
- Alcohol wipe,
- Adhesive bandage, and
- Cotton balls or gauze pads.



7 Select 1 of these injection sites.

- Select the thigh or stomach (except for 2 inches around the belly button).
- Someone else can inject in your thigh, stomach, or back of the upper arm.
- Change injection site each time, shifting the area of the injection to avoid skin irritation.

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



8 Wash your hands thoroughly with soap and water.



9 Clean the injection site with an alcohol wipe.

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

Injecting ENBREL

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

Window should
be visible



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

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

STRETCH



OR

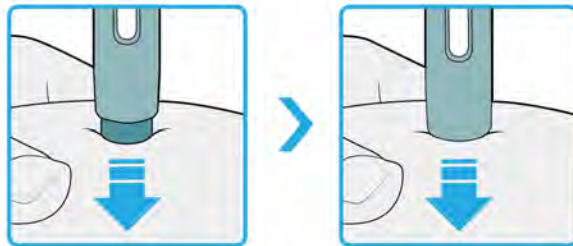
PINCH



- 11** Stretch or pinch the skin to create a firm surface at the injection site until the injection is finished. Place the dark green safety guard straight against the skin.

- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

PUSH
and hold against skin



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

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

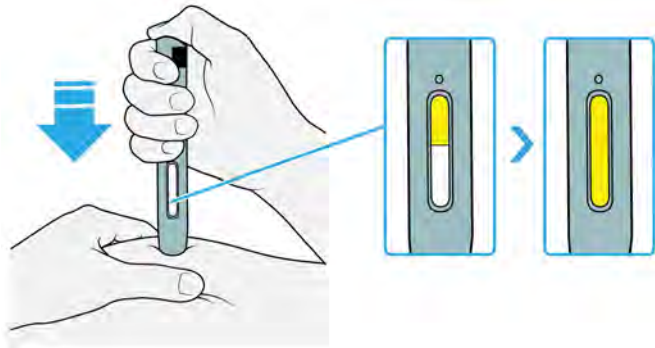
PRESS
purple start button



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

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

WATCH
window will turn fully yellow

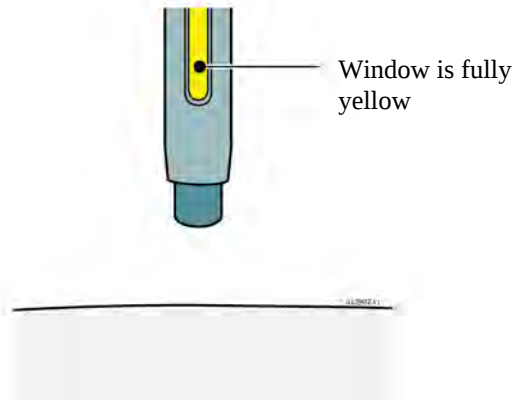


14 Keep pushing the autoinjector down. Wait for the window to turn fully yellow.

- The injection may take up to **15** seconds to complete.
- You may hear or feel a click.
- After the window turns fully yellow, lift the autoinjector away from the skin.
- The dark green safety guard locks around the needle.

Completing the Injection and Disposal

CONFIRM



15 Confirm a full dose of medicine was injected.

- **Do not** touch the dark green safety guard.
- A small drop of liquid on the injection site is okay.

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



16 Check the injection site.

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



17 Place the used autoinjector and white cap in an FDA-cleared sharps disposal.

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

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

Additional information about your sharps disposal container

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

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

Disposing of sharps disposal containers:

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container.

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

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

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

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

Keep the autoinjector and sharps disposal container out of the sight and reach of children.

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

ENBREL (etanercept)

The logo for Amgen, consisting of the word "AMGEN" in a bold, black, sans-serif font. The letters are closely spaced and have a slightly irregular, blocky appearance.

Manufactured by:

Immunex Corporation

Thousand Oaks, CA 91320-1799

U.S. License Number 1132

©1998-2016, 2019-2025 Immunex Corporation. All rights reserved.

1XXXXXX

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

Revised: 6/2025 v21

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.

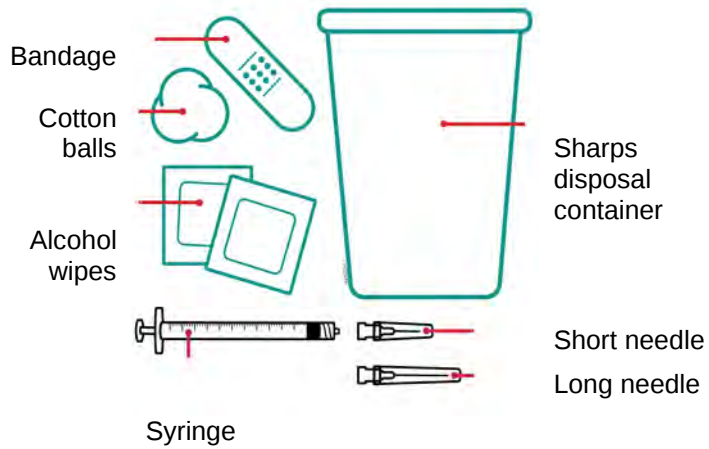
Enbrel is clear and colorless. There may be small white particles in the solution. Check the expiration date.

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.

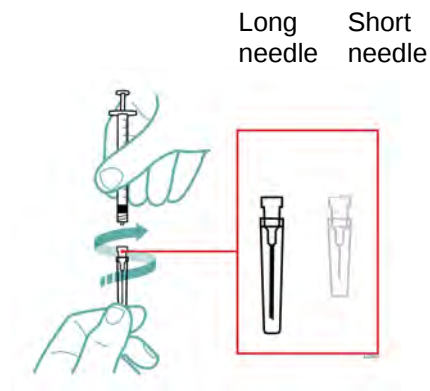
Place the following items on a clean well-lit, flat surface:

- 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.

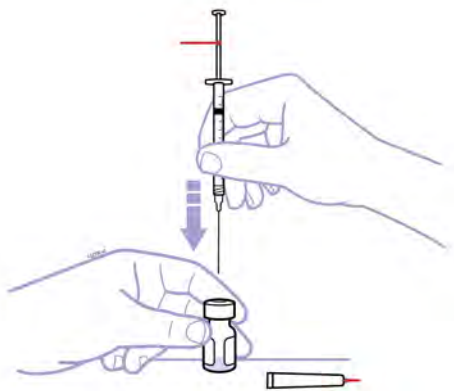
If you require a second single-dose vial, clean the gray stopper of the second single-dose vial with a new alcohol wipe.



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

Step 2: Prepare dose

Plunger



Needle cap

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.

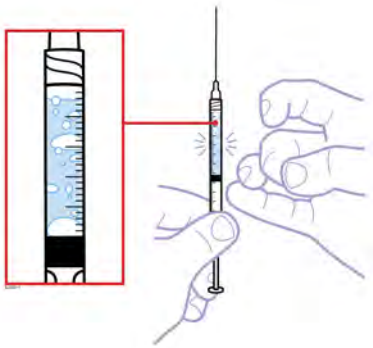
Slowly push 0.5 mL of air into the single-dose vial.



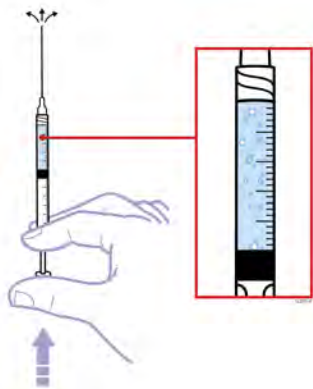
2b. Tilt the single-dose vial to withdraw **all** medicine
 Slowly pull back the plunger to fill the syringe **with all the medicine from the single-dose vial**.

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.

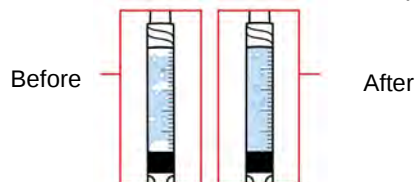
If you need more than 1 single-dose vial to get your **total prescribed dose**, follow these 2 steps:



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.

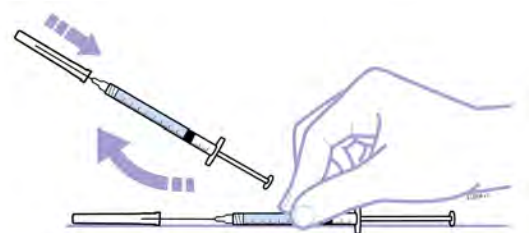
The air will be removed in the next step



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.

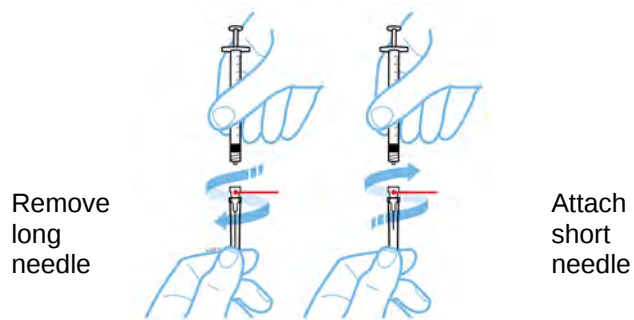


2g. Use 1-handed scoop method to recap. For your safety, place the needle cap on a flat surface.

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



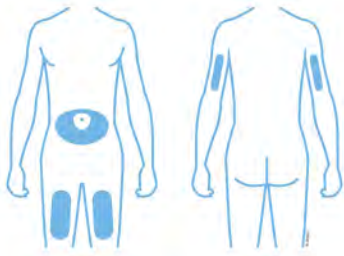
3a. Replace the long needle with the short needle

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.

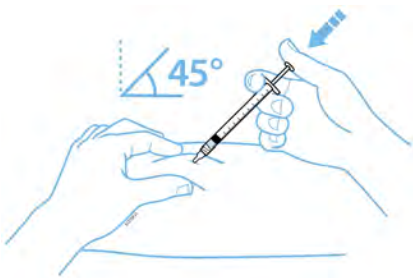


3b. Choose and clean the injection site

- 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.



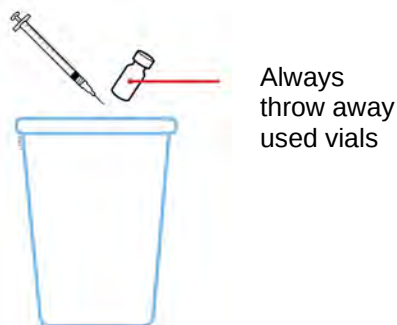
3c. Pinch and inject Enbrel

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.



Manufactured by:

Immunex Corporation
Thousand Oaks, CA 91320-1799
U.S. License Number 1132
© 1998-2020, 2022, 2024 Immunex Corporation. All rights reserved.
[part number]
Revised: 10/2024 v3

 This printed material is recyclable.

Front Panel

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

**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 Enbrel prefilled syringe is not made with natural rubber latex.

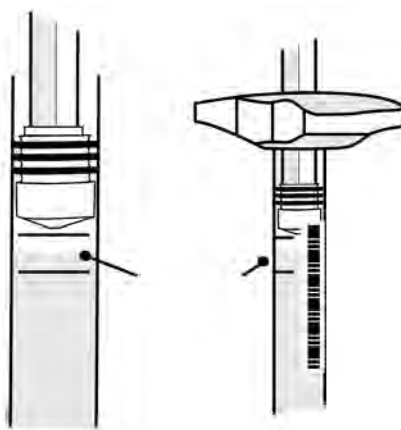
Storage of your Enbrel prefilled syringe

- 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.
 - o 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

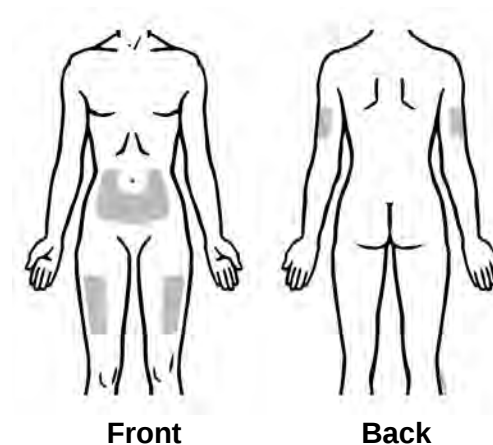
7. Assemble the additional supplies you will need for your injection. These include an alcohol swab, a cotton ball or gauze, and a sharps disposal container (see “**Step 4: Disposing of Supplies**”).
8. Wash your hands with soap and warm water.

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)

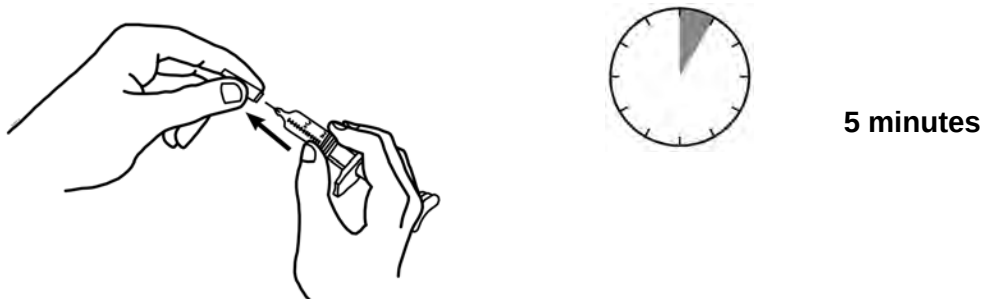


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area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

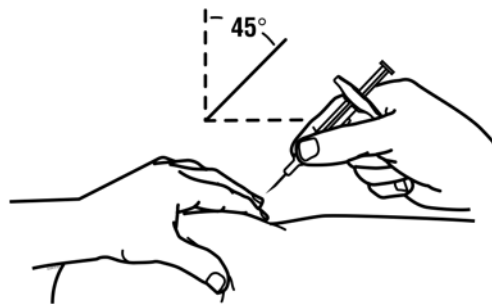
1. Pick up the prefilled syringe from your flat work surface. Hold the barrel of the prefilled syringe with one hand and pull the needle cover straight off, only when you are ready to inject. **Do not** leave the needle cover off for more than **5 minutes**. This can dry out the medicine.



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:
 - o made of a heavy-duty plastic,
 - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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

U.S. License Number 1132

© 1998 – 2016, 2019-2020, 2022-2024 Immunex Corporation. All rights reserved.

1XXXXXX – v13

Revised: 10/2024



This printed material is recyclable.

**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.
 - o 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.**

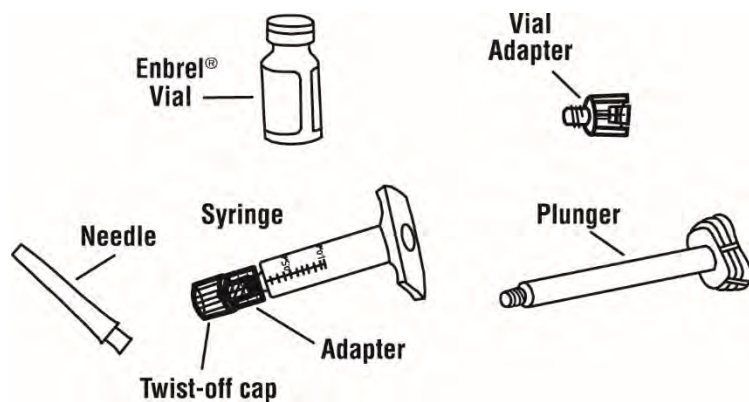
If you have any questions about storage, contact your healthcare provider or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

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.**

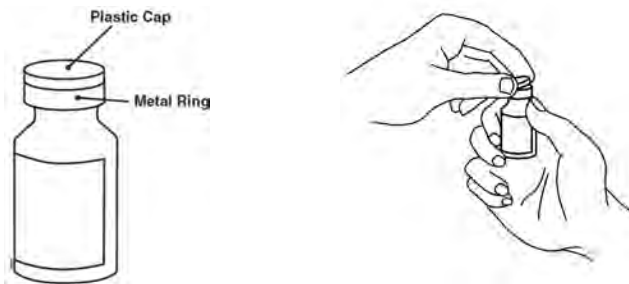
If you are using the vial of Enbrel for more than one dose, you should write the date you mixed the powder and liquid in the area marked "Mixing Date:" on the sticker supplied with these instructions, and attach the sticker to the Enbrel vial.

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.

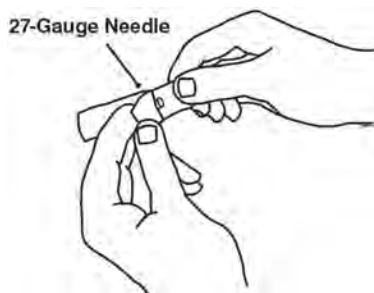
The Enbrel solution must be used within 14 days of the mixing date. You should discard the Enbrel vial and any remaining solution if it is not used within 14 days. **Do not** mix any remaining liquid in one vial of Enbrel solution with another.

STEP 2A: Vial Adapter Method

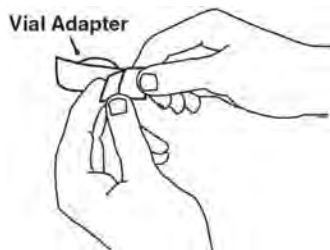
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial.



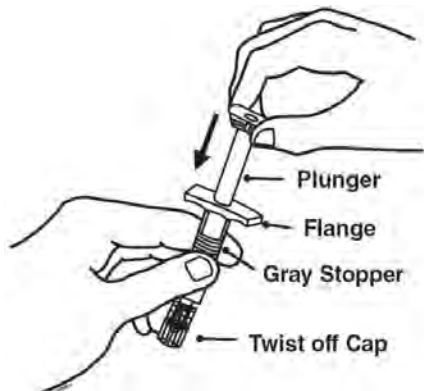
2. Place the Enbrel vial on your flat work surface or turn your dose tray upside down and place your Enbrel vial in the round space marked "V". Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 27-gauge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



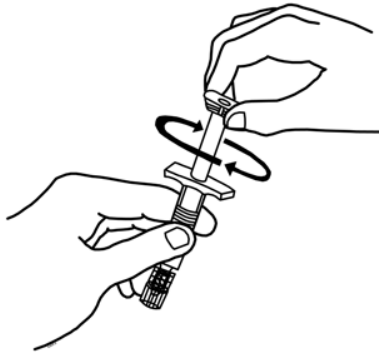
4. Open the wrapper that contains the vial adapter by peeling apart the tabs and set the vial adapter aside for later use. **Do not** touch the vial adapter's twist-on end or the spike inside.



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



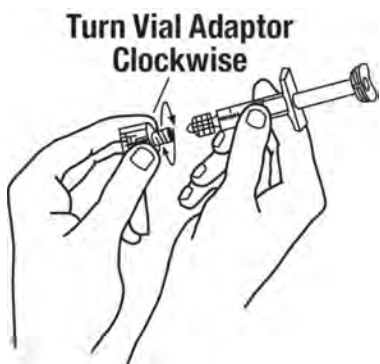
6. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



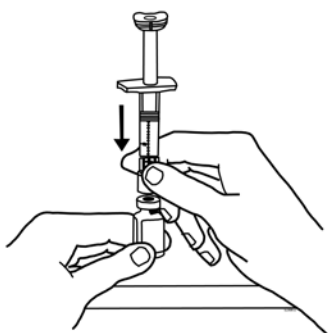
7. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch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



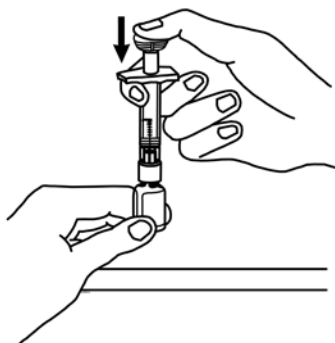
8. Once the twist-off cap is removed, pick up the vial adapter with your free-hand. Twist the vial adapter onto the syringe, turning clockwise until you feel a slight resistance. **Do not over-tighten.**



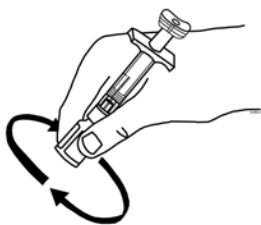
9. Hold the Enbrel vial upright on your flat work surface. Grasp the sides of the vial adapter and place it over the top of the Enbrel vial. **Do not** bump or touch the plunger. Doing so could cause the liquid to leak out. Insert the vial adapter into the gray stopper on the Enbrel vial. The plastic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

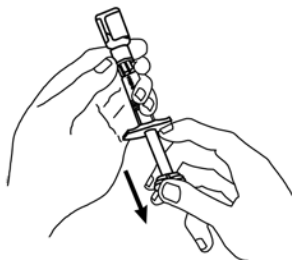


11. Gently swirl the Enbrel vial in a circular motion to dissolve the powder. If you used the dose tray to hold your Enbrel vial, take the vial (with the vial adapter and syringe still attached) out of the dose tray, and gently swirl the vial in a circular motion to dissolve the powder.



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).

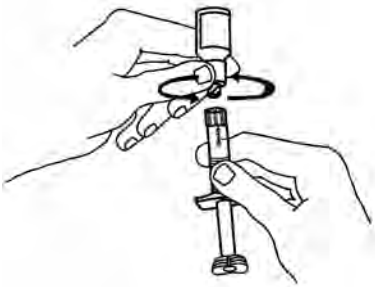
12. Turn the Enbrel vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with your/your child's dose. For adult patients, remove the entire volume (1 mL), unless otherwise instructed by your healthcare provider.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



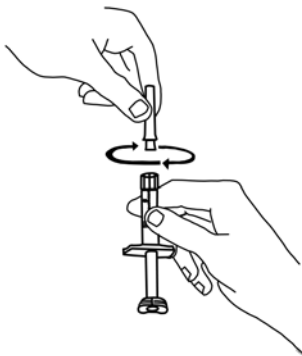
13. Check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to again draw the correct amount of solution back into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

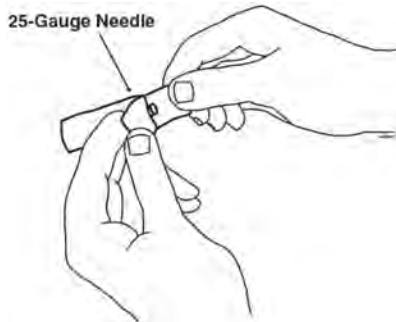
Step 2B: Free-Hand Method

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.

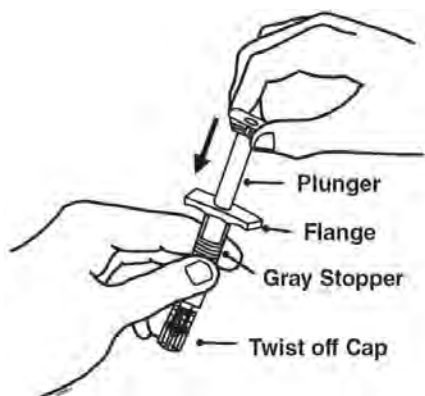
1. Remove the pink plastic cap from the Enbrel vial. **Do not** remove the gray stopper or silver metal ring around the top of the Enbrel vial. Write the date you mix the powder and solution on the supplied "Mixing Date:" sticker and attach it to the Enbrel vial.



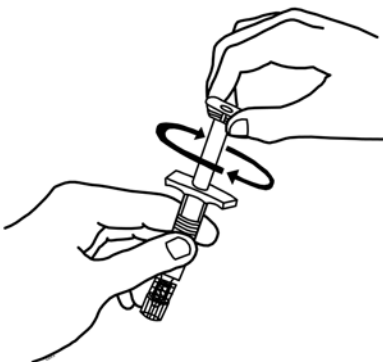
2. Place the Enbrel vial on your flat work surface. Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do not** touch the gray stopper with your hands.
3. Open the wrapper that contains the 25-gauge needle by peeling apart the tabs and set the needle aside for later use. The 25-gauge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



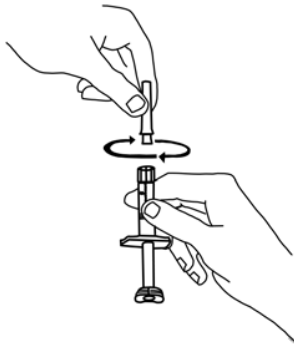
5. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until you feel a slight resistance.



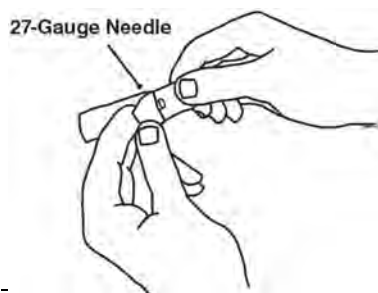
6. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do not** touch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



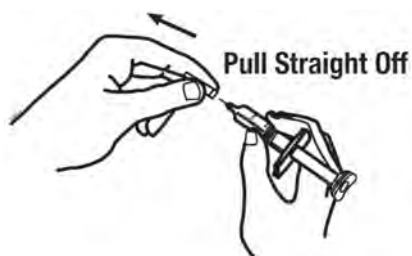
7. Continue to hold the barrel of the syringe. With your free-hand, twist the 25-gauge needle onto the tip of the syringe until it fits snugly. Place the syringe on your flat work surface.



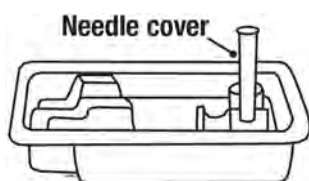
8. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use. The 27-gauge needle will be used to inject the dose.



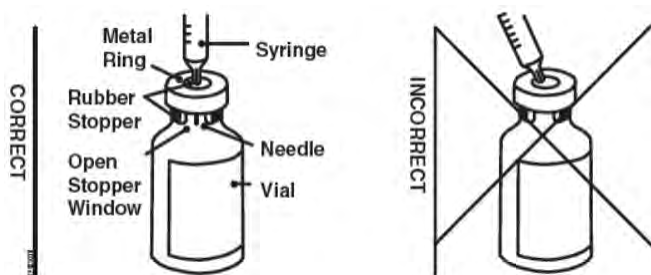
9. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand, and pull the needle cover straight off. To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it. **Do not** touch the needle or allow it to touch any surface. **Do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



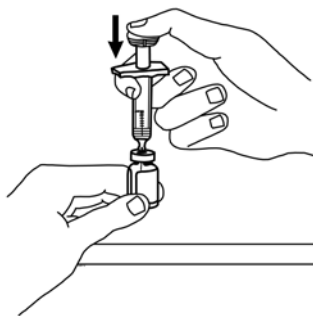
10. Place the needle cover (open side up) in the round space marked “N” in the Enbrel dose tray.



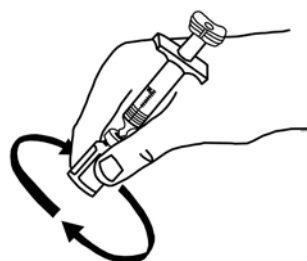
11. Place the Enbrel vial on your flat work surface. Hold the syringe with the needle facing up, and gently pull back on the plunger to pull a small amount of air into the syringe. Then, insert the needle straight down through the center ring of the gray stopper (see illustrations). You should feel a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

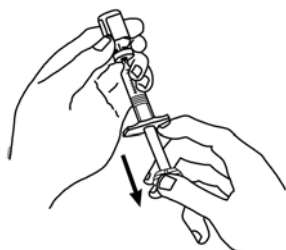


13. Leave the syringe in place. Gently swirl the Enbrel vial in a circular motion to dissolve the powder.

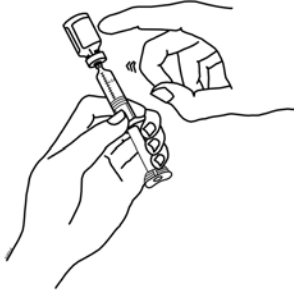


Do not shake. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do not inject the solution if it is discolored, contains lumps, flakes, or particles.**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

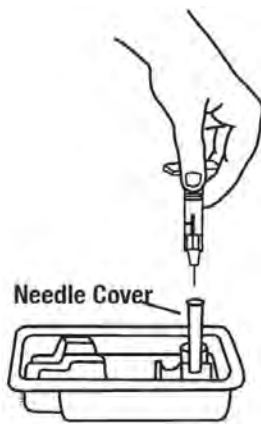
14. With the needle in the Enbrel vial, turn the vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with the correct dose. Make sure to keep the tip of the needle in the solution. Some white foam may remain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

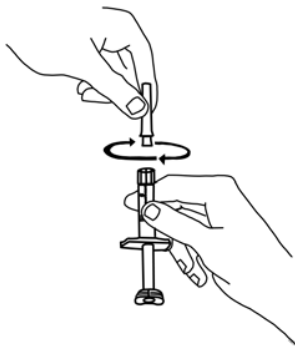


16. Remove the syringe and needle from the Enbrel vial. Keep the needle attached to the syringe and insert the 25-gauge needle straight down into the needle cover in the Enbrel dose tray.



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

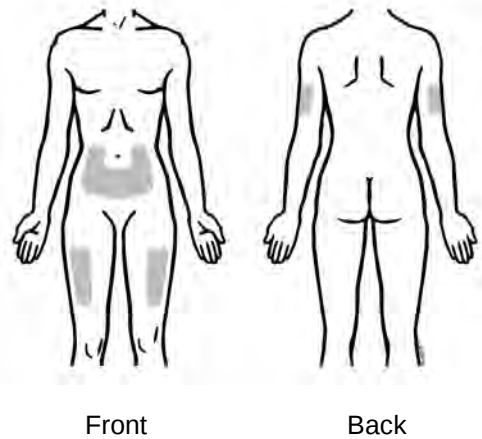
correctly lined up with the center of the stopper, you will feel constant resistance as it goes through the stopper and no “pop”. The needle may enter at an angle and bend, break, or prevent proper withdrawal of Enbrel solution from the vial.

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)

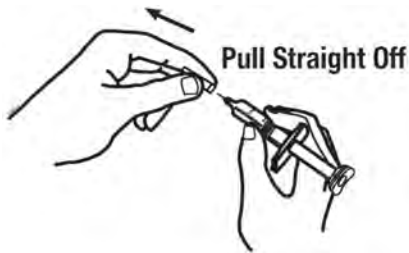


2. Rotate the site for each injection. **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should not inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area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

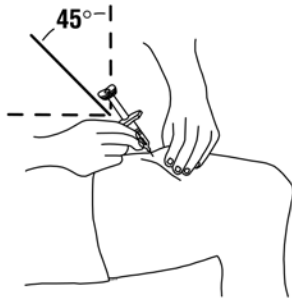
Step 5: Injecting the Enbrel Solution

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:
 - o made of a heavy-duty plastic,
 - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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

© 1998 – 2016, 2019 Immunex Corporation. All rights reserved.

1XXXXXX – v9

Revised: 10/2019

 This printed material is recyclable.



Flip over for
additional information

INSTRUCTIONS FOR USE

ENBREL® [en-brel]

(etanercept)

injection, for subcutaneous use

50 mg/mL

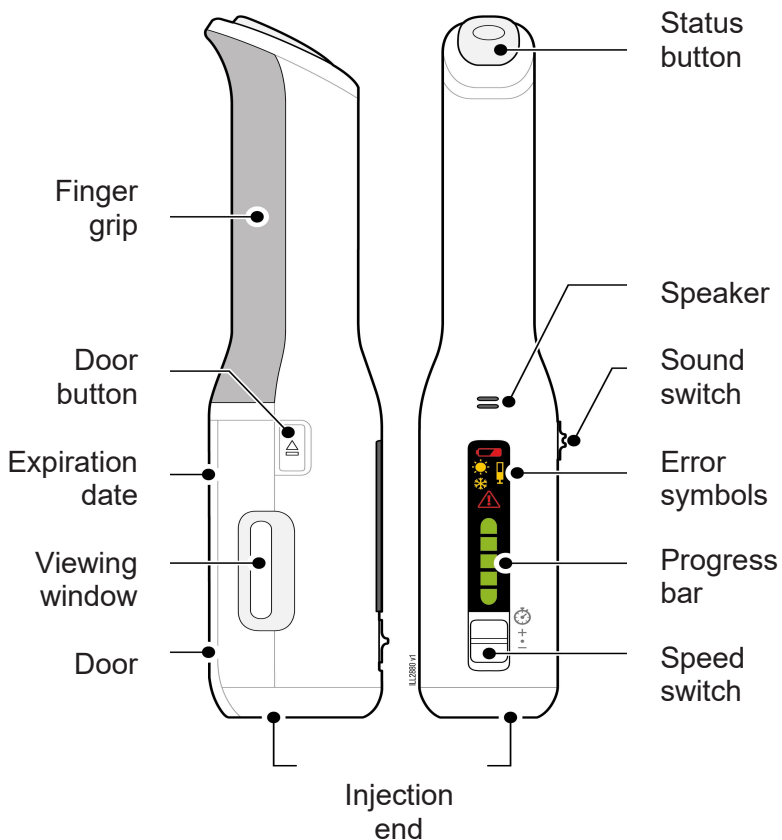
**ENBREL Mini® Single-dose Prefilled Cartridge
for use with all AutoTouch® Reusable Autoinjectors**

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

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

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

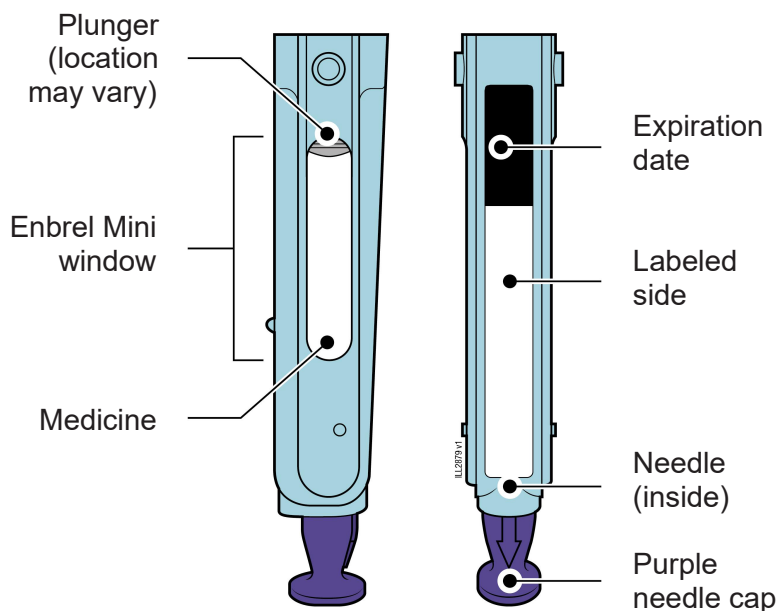
AutoTouch® Reusable Autoinjector





To learn more about autoinjector features, see the User Manual, section "Guide to Parts."

Enbrel Mini® Single-dose Prefilled Cartridge



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



To learn more about cartridge features, see the User Manual, section "Guide to Parts."

Frequently asked questions

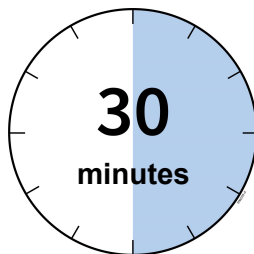
For additional information and answers to frequently asked questions, visit www.enbrel.com.

Where to get help

If you want more information or help using ENBREL:

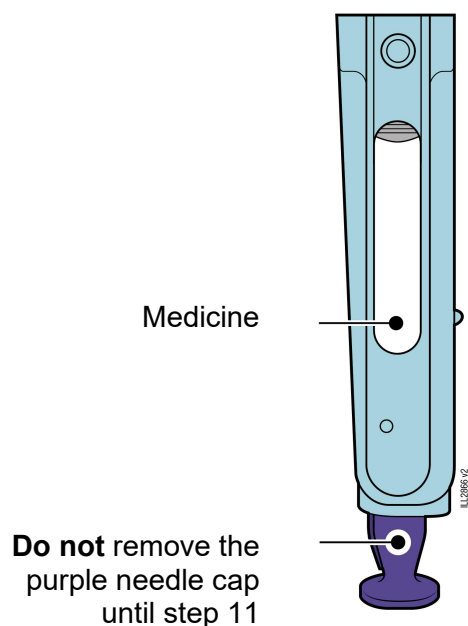
- Contact your healthcare provider,
- Visit www.enbrel.com, or
- Call 1-888-4ENBREL (1-888-436-2735).

WAIT



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

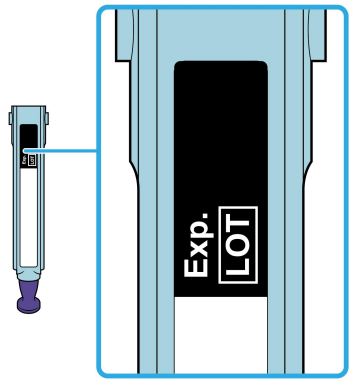
- Remove 1 cartridge from the carton in the refrigerator.
- Put the carton containing any unused cartridges back in the refrigerator.
- Let the cartridge warm up naturally.
- **Do not** heat the cartridge with hot water, a microwave, or direct sunlight.
- **Do not** put the cartridge back in the refrigerator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



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

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

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



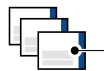
Expiration date

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

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



Sharps
disposal
container



3 Alcohol
wipes



Adhesive Bandage



Cotton balls
or gauze pads

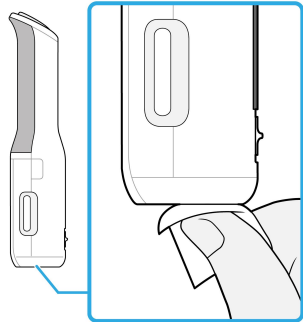
4 Gather and place the following items for the injection on a clean, flat, and well-lit surface:

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



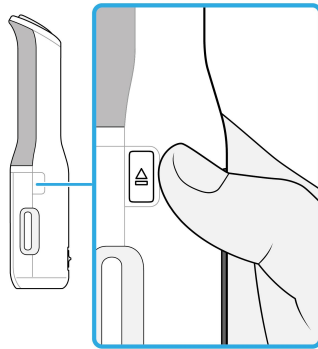
- 5 Wash your hands thoroughly with soap and water.**

Getting Ready to Inject ENBREL

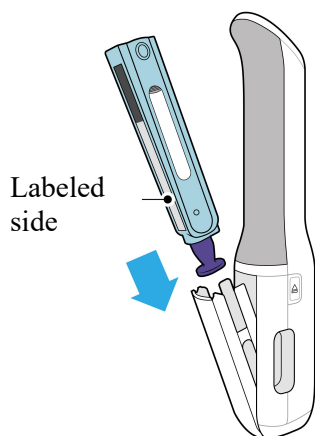


- 6 Clean the injection end of the autoinjector with an alcohol wipe.**

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



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

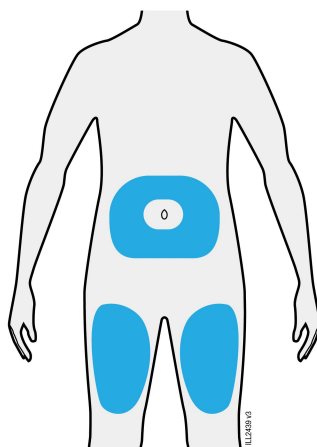


8 Insert the cartridge with the purple needle cap down and the labeled side facing out.

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



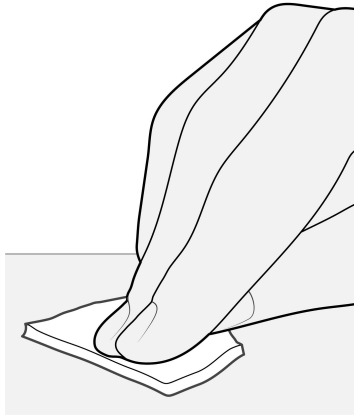
If the status button flashes red, see the User Manual, section "Troubleshooting."



9 Select 1 of these injection site locations.

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

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

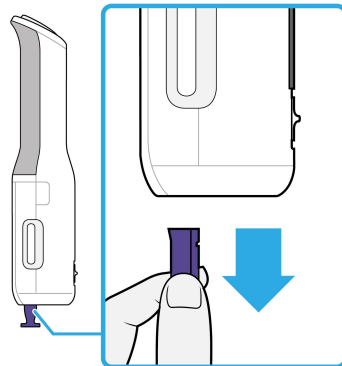


10 Clean the injection site with a new alcohol wipe.

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

Injecting ENBREL

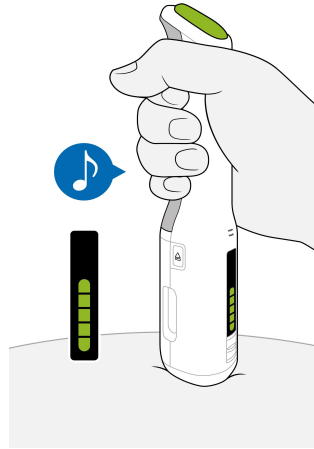
Important: Only remove the purple needle cap when you can inject right away (within 5 minutes) as the medicine can dry out. **Do not** recap.



11 Pull the purple needle cap straight down to remove.

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

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



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

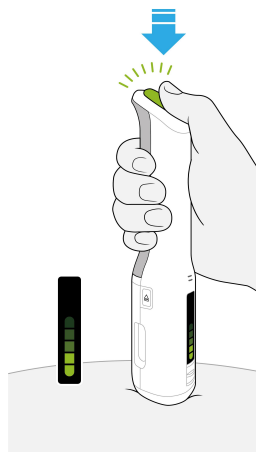
- After placing on the skin, wait for the:
 - status button to turn green,
 - progress bar to turn green, and
 - chime sound (will not chime if sound switch is off).
- **Do not** stretch or pinch the injection site.



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

Be patient.

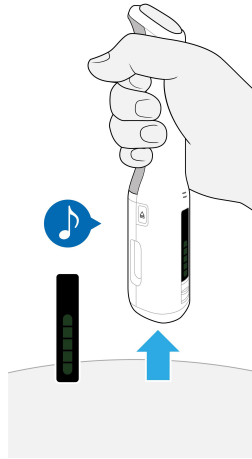
The injection
may take up
to **20 seconds**.



13 Press and release the status button to inject.

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

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

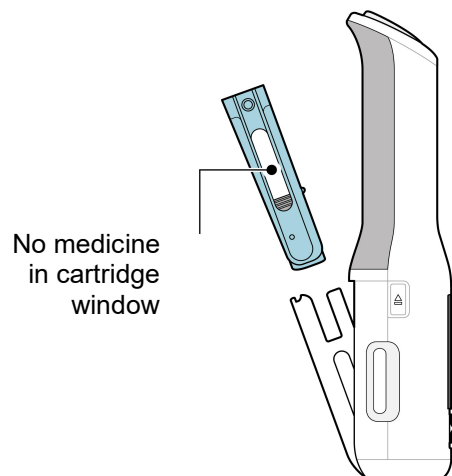


14 Keep holding flat on the skin until the status button and progress bar turn off.

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

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

Completing the Injection



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

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

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

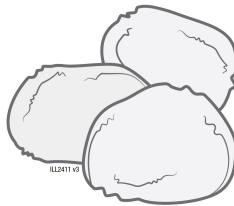
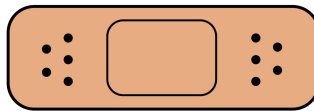


16

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

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

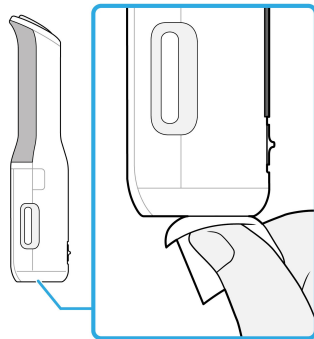
Important: Always keep the sharps disposal container out of the reach of children.



17

Check the injection site.

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



18

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

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

Additional information about your sharps disposal container

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

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

Disposing of sharps disposal containers:

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container.

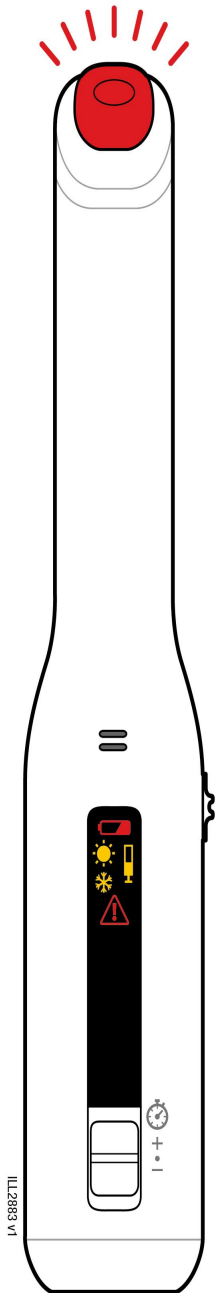
There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

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

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.



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



Low battery:

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

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

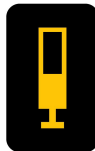
See the User Manual, section "Troubleshooting", for more information.



Needle exposure:

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

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



Enbrel Mini problem:

There are several reasons you might get this error.

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



Battery dead:

The battery is dead.

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

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



Too hot or too cold:

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

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

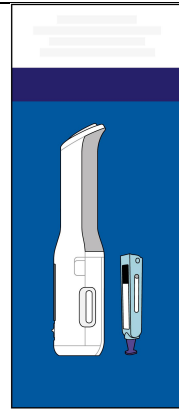
See the User Manual, section "Troubleshooting", for more information.



Autoinjector detected problem:

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

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



Flip over for additional information



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

Important Information You Need to Know Before Injecting ENBREL

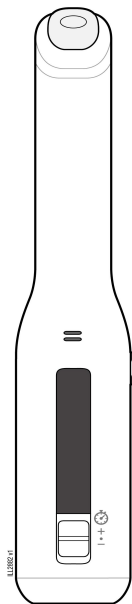
The AutoTouch reusable autoinjector is used with the Enbrel Mini single-dose prefilled cartridge to administer your dose of ENBREL. The Enbrel Mini single-dose prefilled cartridge contains one 50 mg single-dose of ENBREL.

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

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

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

AutoTouch® Reusable Autoinjector Storage and Handling



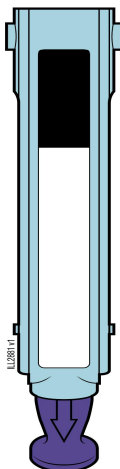
- Store the autoinjector at room temperature in a dry, safe place, such as a cabinet or drawer at 50°F to 104°F (10°C to 40°C).
- **Do not** store the autoinjector in the refrigerator with the cartridge.
- Use an alcohol wipe to clean the bottom (injection end) before and after each use.



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

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

Enbrel Mini® Cartridge Storage and Handling



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

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

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

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

Personalized patient support designed for you.

AMGEN Support⁺

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

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



Scan the QR code for more information

Additional Support

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



ENBRELinjection.com



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

©2026 Immunex Corporation. All rights reserved.

Issued 02/2026
Version: 10