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

Before use

Purple start button
Expiration Date

Window

Medicine

White cap on

Important: Needle is inside

After use

Expiration Date

Yellow window (injection complete)

Green safety guard
White cap off
Important

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

Storing your Enbrel SureClick autoinjectors

- Store Enbrel SureClick autoinjector in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store 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.
- Do not store the Enbrel SureClick autoinjector in extreme heat or cold. For example, avoid storing 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 contain 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.

White cap on                       Window                    Medicine

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.

You can use:
- Your thigh
- Stomach area (abdomen), except for a 2-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 when you are ready to inject.

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 remove the white cap from the autoinjector until you are ready to inject.

F  Stretch or pinch your injection site to create a firm surface.

Stretch method

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

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

**Important:** Keep the skin stretched or pinched while injecting.

**Step 3: Inject**

**G** Hold the stretch or pinch. With the white cap off, **place** the autoinjector on your skin at 90 degrees.

**Important:** 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.

![](image1)

J  Keep **pushing** down on your skin. Your injection could take about **15** seconds.

![](image2)

**Note:** After you remove 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:
  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 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.

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<part number>

Revised: 11/2016 v11
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 Enbrel prefilled syringe

- Store Enbrel prefilled syringe in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store 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 Enbrel prefilled syringe has reached room temperature, do not put it back in the refrigerator.
- Throw away Enbrel prefilled syringe that has been stored at room temperature after 14 days.
- Do not store 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.

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. 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.

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1XXXXXXXX – v7
Revised: 11/2016
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.

![Plastic Cap and Metal Ring](image)

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.

![27-Gauge Needle](image)

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.

![Vial Adapter](image)
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.

![Image of Enbrel vial swirling](image)

**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.

![Image of Enbrel vial upside down](image)

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.

![Image of Enbrel vial upside down with air bubbles](image)
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.

![Image of syringe being removed from vial adapter]

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.

![Image of needle being twisted onto syringe]

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.

![Plastic Cap and Metal Ring](Image)

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.

![25-Gauge Needle](Image)

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

![Plunger, Flange, Gray Stopper, Twist-off Cap](Image)
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.

![Image of needle being inserted into needle cover]

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.

![Image of needle being twisted onto syringe]

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.

![Pull Straight Off]

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.

![45°]

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.

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