

Instructions for Use
Enbrel[®] (en-brel)
(etanercept)
Single-use Prefilled SureClick[®] Autoinjector

How do I prepare and give an injection with Enbrel Single-use Prefilled SureClick Autoinjector?

This section contains information on how to properly use the Enbrel SureClick autoinjector. It is important that you **do NOT** try to give yourself the injection unless you have received special training from your doctor, nurse, or pharmacist.

A single-use prefilled SureClick autoinjector contains one 50 mg dose of Enbrel.

Children must weigh at least 138 pounds to use Enbrel single-use prefilled SureClick autoinjector. Children who weigh less than 138 pounds should use a different form of Enbrel.

IMPORTANT: The needle cap on the single-use prefilled SureClick autoinjector contains a needle cover that is composed of dry natural rubber, which is made from latex. Tell your doctor if you are allergic to latex.

Equipment:

- A new Enbrel SureClick autoinjector, and
- Alcohol wipes or similar
- Cotton ball or gauze
- Sharps disposal container

Storage of Enbrel

- Enbrel should be refrigerated at 36°F to 46°F (2°C to 8°C). Store Enbrel in the original carton to protect from light or physical damage.
- If needed, you may store your Enbrel SureClick autoinjector at room temperature at 68°F to 77°F (20°C to 25°C) for up to 14 days.
 - Once Enbrel has reached room temperature, do not put it back in the refrigerator.
- Throw away Enbrel that has been stored at room temperature after 14 days.

- **Do NOT** store Enbrel in extreme heat or cold. For example, avoid storing Enbrel in your vehicle's glove box or trunk. **Do NOT freeze.**
- **Keep Enbrel and all medicines out of the reach of children.** If you have any questions about storage, contact your doctor, nurse, or pharmacist, or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

Preparing for an Enbrel Injection

- Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.
- Remove one single-use prefilled Enbrel SureClick autoinjector from the carton. Carefully lift the autoinjector straight up out of the box. **Do NOT** shake the autoinjector. Place the carton containing any remaining autoinjectors back into the refrigerator (36° to 46°F [2° to 8°C]).
- Check the expiration date on the autoinjector label. If the expiration date has passed, **do NOT** use the autoinjector and contact your pharmacist or call 1-888-4ENBREL (1-888-436-2735) for assistance.
- The syringe in your Enbrel autoinjector may break if you drop it onto a hard surface. You may not be able to see that the syringe in your Enbrel autoinjector is cracked or broken. If you drop it onto a hard surface, **do NOT** use the autoinjector. Use a new autoinjector for your injection.
- **Do NOT** use the autoinjector if the white needle cap is missing or not securely attached. Call 1-888-4ENBREL (1-888-436-2735).
- Look at Enbrel through the inspection window. It should be clear and colorless, or may have small white particles. **Do NOT** inject Enbrel if it looks cloudy, discolored, or has large lumps, flakes, or colored particles. Call 1-888-4ENBREL (1-888-436-2735). Use a new autoinjector for your injection.
- For a more comfortable injection, leave the autoinjector at room temperature for about 15 to 30 minutes before injecting. **Do NOT** remove the white needle cap 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).
- Wash your hands thoroughly.
- **Do NOT** remove the white needle cap from the autoinjector until you are ready to inject.



Choosing and Preparing an Injection Site

Choose an Injection Site

The injection site must be firm for the autoinjector to work properly. The preferred injection site for Enbrel using a prefilled SureClick autoinjector is the front of the thigh.

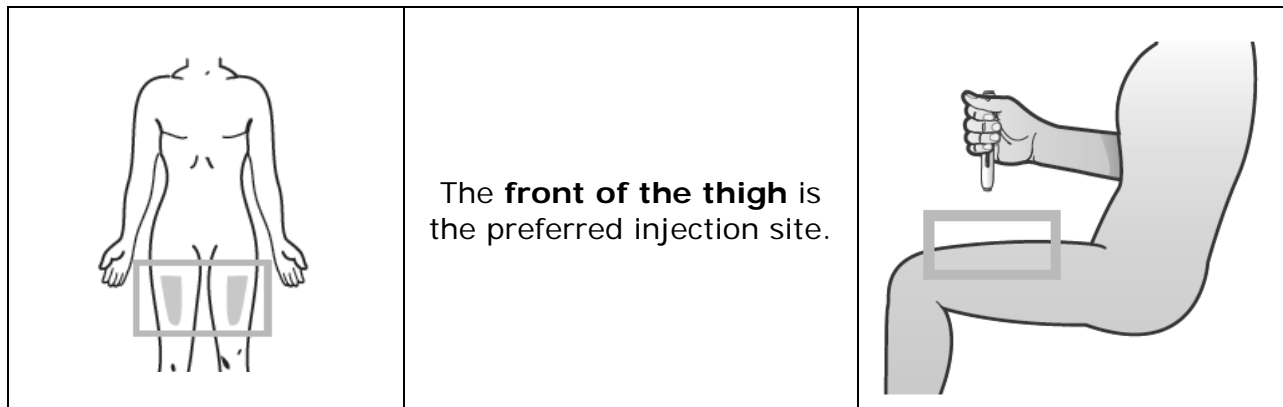
- **Rotate Injection Location**

Rotate the site for each injection. **Do NOT** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with stretch marks.

- **Patients with Psoriasis**

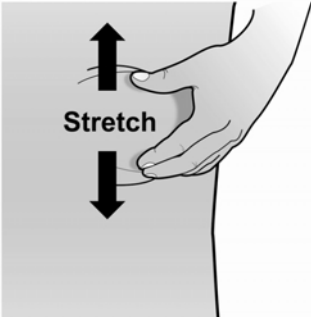
If you have psoriasis, you should **NOT** inject directly into any raised, thick, red, or scaly skin patches or lesions.

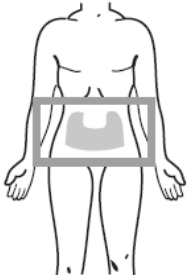
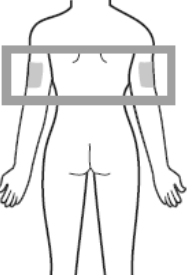
Instructions for Preferred Injection Site



Instructions for Alternate Injection Sites

When using alternate injection sites, it is particularly important to create enough firmness on the site to be able to successfully complete the injection.

	<p>Stretch technique</p> <p>Make sure the skin under and around the prefilled autoinjector is firm and taut to provide enough resistance to fully retract the safety guard and unlock the prefilled autoinjector.</p>
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	<p>You can use the abdomen, except for the two-inch area right around the navel. <u>Stretch the skin</u> at the injection site to create a <u>firm and taut surface</u>.</p>
	<p>If someone else is giving you the injection, they can also use the outer area of the upper arms. For the upper arms, it is recommended to <u>stretch the skin</u> at the injection site to create a <u>firm and taut surface</u>.</p>

Prepare the Site

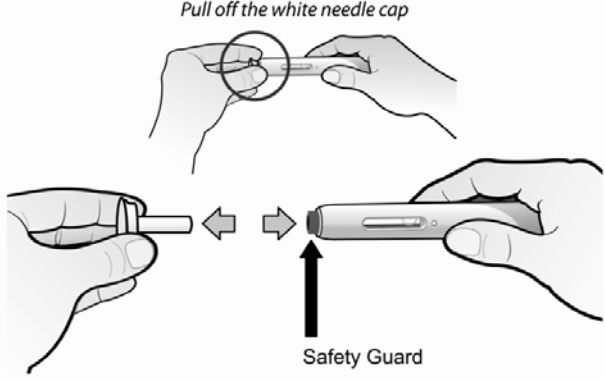
To prepare the area of skin where Enbrel is to be injected, wipe the injection site with an alcohol swab. **Do NOT touch this area again before giving the injection.**

Injecting Enbrel Using a Single-use Prefilled SureClick Autoinjector

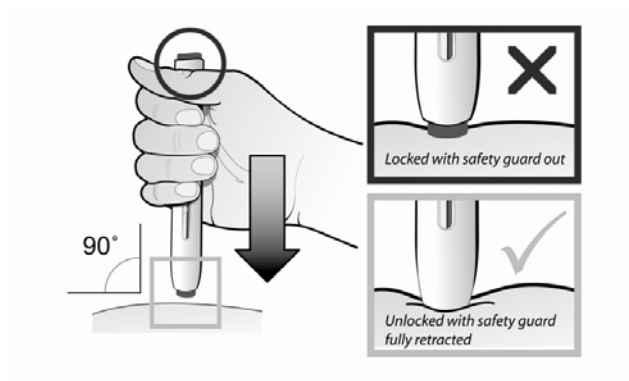
⊘ **Do NOT** remove the white needle cap from the autoinjector until you are ready to inject.

1. **Pull the white needle cap straight off.** To avoid damaging the needle inside the autoinjector, **do NOT** twist or bend the white needle cap while you are removing it, and **do NOT** try to put the white needle cap back onto the autoinjector.

When you remove the white needle cap, there may be a drop of liquid at the end of the needle or safety guard; this is normal.

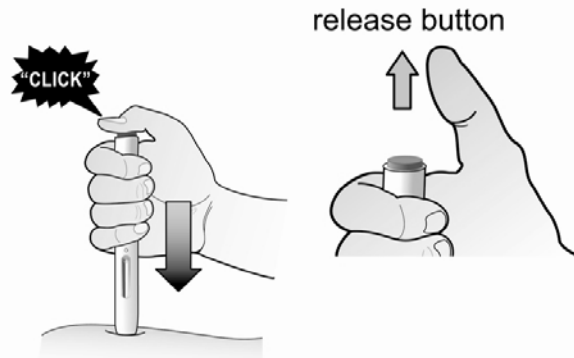
	<ul style="list-style-type: none">⊘ Do NOT twist or bend the white needle cap.⊘ Do NOT re-attach the white needle cap onto the prefilled autoinjector. <hr/> <ul style="list-style-type: none">✓ Do pull the white needle cap straight off.
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2. **Do NOT touch the purple button. Press prefilled autoinjector onto skin to unlock safety guard.**



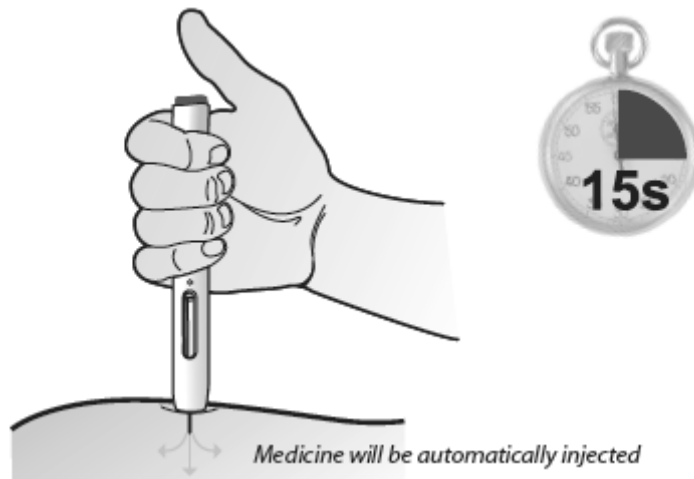
<ul style="list-style-type: none">⊘ Do NOT press the purple button until the safety guard is fully retracted. <hr/> <ul style="list-style-type: none">✓ Do keep enough downward pressure to fully retract the purple safety guard and to keep the purple button unlocked.✓ Do hold the prefilled autoinjector at a right angle (90°) at the injection site.

3. Briefly press and release purple button.



✓ **Do** maintain pressure on the skin during the injection.

4. Count slowly to 15 seconds for injection to end and check window to confirm delivery of full dose.

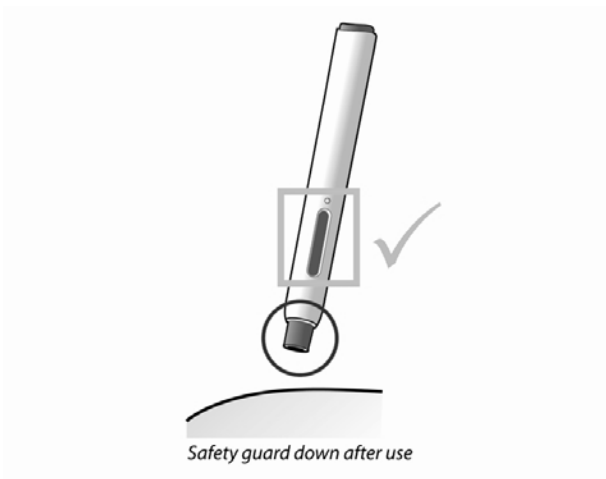


⊘ **Do NOT** move the prefilled autoinjector during the injection.

- ✓ **Do** wait for the injection to finish before releasing pressure.
- ✓ **You might hear a second click as the purple button pops back up.**

After the Injection

- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.
- **Do NOT** rub the injection site. If needed, you may cover the injection site with a bandage.



- ✓ **Do** check the inspection window to confirm it has turned purple.
- ! If the inspection window is not purple, call your healthcare provider.

Remember

If you have any problems, please call 1-888-4ENBREL (1-888-436-2735) for assistance.

Disposing of Supplies

The SureClick autoinjector should **NEVER** be reused.

Dispose of the used autoinjector as instructed by your healthcare provider, or by following these steps:

- **Do NOT** throw the used autoinjector in the household trash or recycle.
- Place the used autoinjector in a hard plastic disposal container with a screw-on cap or a metal container with a plastic lid, such as a coffee can, labeled "used syringes." If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard plastic container is used, always screw the cap on tightly after each use. **Do NOT** use glass or clear plastic containers. Sharps disposal containers may also be purchased at your local pharmacy.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.

- You should always check first with your healthcare provider for instructions on how to properly dispose of a filled disposal container. There may be special state and local laws for disposing of used needles and syringes, including autoinjectors. **Do NOT throw the disposal container in household trash. Do NOT recycle.**
- **Always** keep the 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.

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



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Immunex Corporation
Thousand Oaks, CA 91320-1799
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PMV7

Instructions for Use
Enbrel[®] (en-brel)
(etanercept)
Single-use Prefilled Syringe

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

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

- The 50 mg single-use prefilled syringe that contains one 50 mg dose of Enbrel.
- The 25 mg single-use prefilled syringe that contains one 25 mg dose of Enbrel.

Your doctor will tell you which one to use.

A 50 mg dose can be given as one injection using a 50 mg single-use prefilled syringe or as two injections using 25 mg single-use prefilled syringes. Your doctor will tell you whether the two injections with 25 mg single-use 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 single-use prefilled syringe. Children who weigh less than 138 pounds should use a different form of Enbrel. The Enbrel 25 mg single-use prefilled syringe should NOT be used in pediatric patients weighing less than 68 pounds.

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

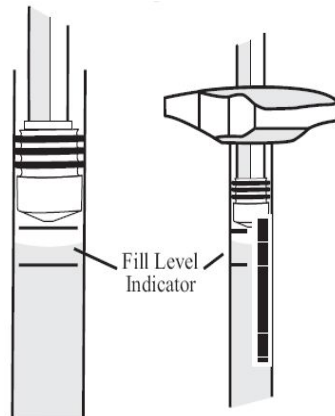
Storage of Enbrel

- Enbrel should be refrigerated at 36°F to 46°F (2°C to 8°C). Store Enbrel 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 has reached room temperature, do not put it back in the refrigerator.
- Throw away Enbrel that has been stored at room temperature after 14 days.
- **Do NOT** store Enbrel in extreme heat or cold. For example, avoid storing Enbrel in your vehicle's glove box or trunk. **Do NOT freeze.**

- **Keep Enbrel and all medicines out of the reach of children.** If you have any questions about storage, contact your doctor, nurse, or pharmacist or call 1-888-4ENBREL (1-888-436-2735) for further instructions.

STEP 1: Setting Up for an Injection

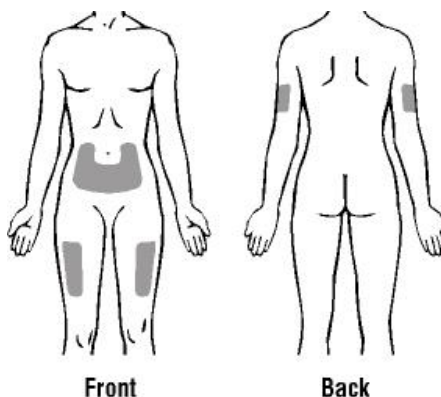
1. Select a clean, well-lit, flat work surface, such as a table.
2. Take the Enbrel carton containing the prefilled syringes out of the refrigerator and place it on your flat work surface. Remove one prefilled syringe and place it on your work surface. Carefully lift the prefilled syringe straight up out of the box. **Do NOT** shake the prefilled syringe of Enbrel. Place the carton containing any remaining prefilled syringes back into the refrigerator (36° to 46°F [2° 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.
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. Three recommended injection sites for Enbrel using a prefilled syringe include: (1) the front of the middle thighs; (2) the abdomen, except for the two-inch area right around the navel; and, (3) the outer area of the upper arms.



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 (“psoriasis skin 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.**

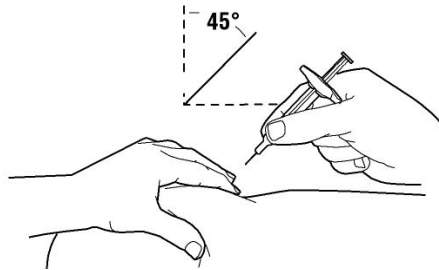
STEP 3: Injecting Enbrel Using a Prefilled Syringe

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. Insert the needle at a slight angle (45 degrees) to the skin. With a quick, "dart-like" motion, insert the needle 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.

Dispose of the used syringe as instructed by your healthcare provider, or by following these steps:

- **Do NOT** throw the used syringe in the household trash or recycle.
- Place the used syringe in a hard plastic disposal container with a screw-on cap or a metal container with a plastic lid, such as a coffee can, labeled “used syringes.” If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard plastic container is used, always screw the cap on tightly after each use. **Do NOT** use glass or clear plastic containers. Sharps disposal containers may also be purchased at your local pharmacy.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- You should always check first with your healthcare provider for instructions on how to properly dispose of a filled disposal container. There may be special state and local laws for disposing of used needles and syringes. **Do NOT throw the disposal container in household trash. Do NOT recycle.**
- **Always** keep the 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.

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



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Thousand Oaks, CA 91320-1799
Marketed by Amgen Inc.

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PMV6

Instructions for Use
Enbrel® (en-brel)
(etanercept)
Multiple-use Vial

How do I prepare and give an injection with Enbrel Multiple-use Vial?

A multiple-use vial contains 25 mg of Enbrel.

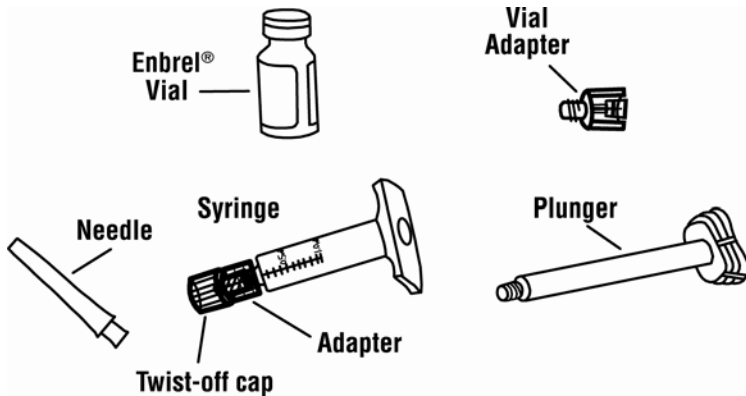
Storage of Enbrel

- Enbrel should be refrigerated at 36°F to 46°F (2°C to 8°C). Store Enbrel in the original carton to protect from light or physical damage.
- If needed, you may store your Enbrel Multiple-use Vial and diluent syringe at room temperature between 68°F to 77°F (20°C to 25°C) for up to 14 days.
- Throw away Enbrel that has been stored at room temperature after 14 days.
- Mixed (reconstituted) Enbrel powder, 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 in extreme heat or cold. For example, avoid storing Enbrel in your vehicle's glove box or trunk. **Do NOT** freeze.
- **Keep Enbrel and all medicines out of the reach of children.** If you have any questions about storage, contact your doctor, nurse, or pharmacist 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 five 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**

Adult patients 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.**

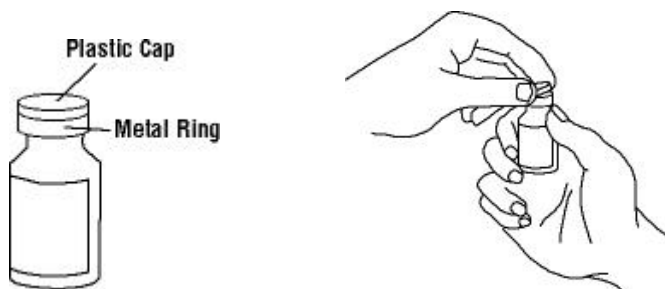
If you are using the vial of Enbrel for more than one dose, you should write the date you mixed the powder and liquid in the area marked "Mixing Date:" on the sticker supplied with these instructions, and attach the sticker to the Enbrel vial.

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 doctor, nurse, or pharmacist, 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.

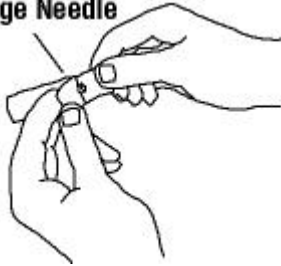


2. Place the Enbrel vial on your flat work surface or turn your dose tray upside down and place your Enbrel vial in the round space marked "V". Use one alcohol

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.

27-Gauge Needle

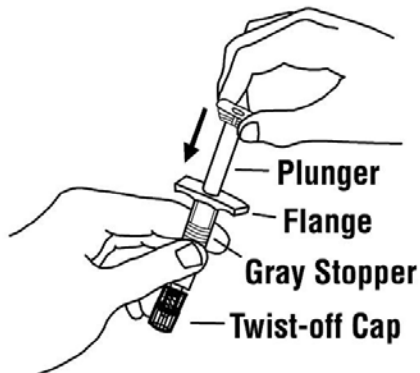


4. Open the wrapper that contains the vial adapter by peeling apart the tabs and set the vial adapter aside for later use. **Do NOT** touch the vial adapter's twist-off end or the spike inside.

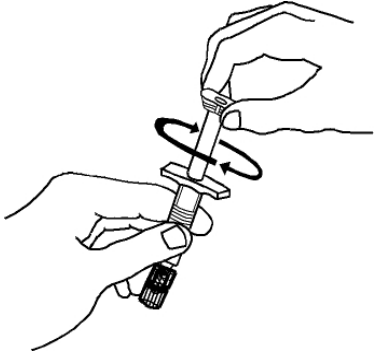
Vial Adapter



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



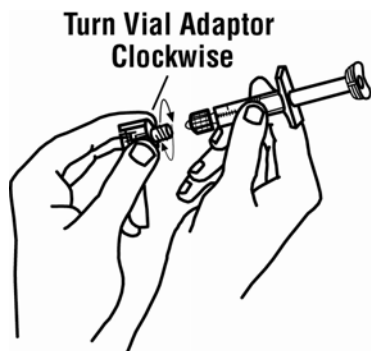
6. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until a slight resistance is felt.



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.

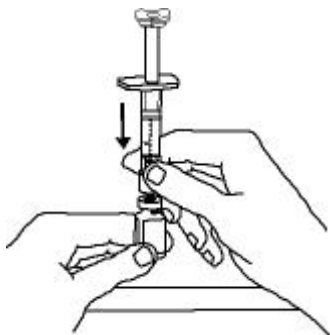


8. Once the twist-off cap is removed, pick up the vial adapter with your free hand. Twist the vial adapter onto the syringe, turning clockwise, until a slight resistance is felt. **Do NOT over-tighten.**

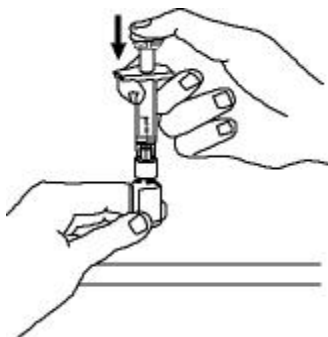


9. Hold the Enbrel vial upright on your flat work surface. Grasp the sides of the vial adapter and place it over the top of the Enbrel vial. **Do NOT** bump or touch

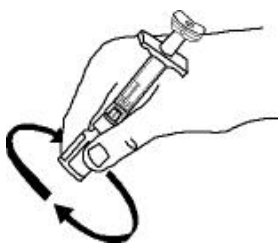
the plunger. Doing so could cause the liquid to leak out. Insert the vial adapter into the gray stopper on the Enbrel vial. The plastic spike inside the vial adapter should puncture the gray stopper. The vial adapter should fit snugly.



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.

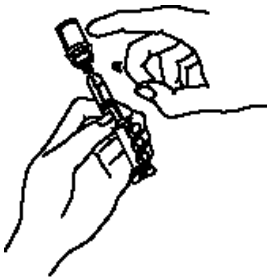


DO NOT SHAKE. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do NOT inject the solution if it is discolored, contains lumps, flakes, or particles.**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

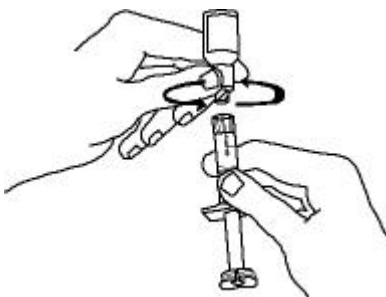
12. Turn the Enbrel vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with your/your child's dose. For adult patients, remove the entire volume (1 mL), unless otherwise instructed by your doctor. Be careful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



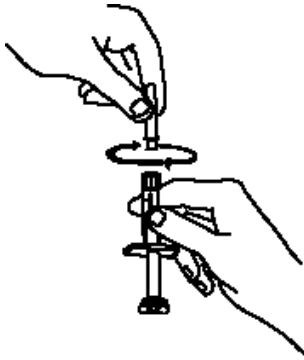
13. Check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger to again draw the correct amount of solution back into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

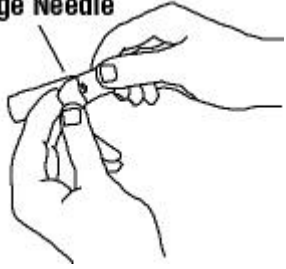
If you are preparing a dose from an Enbrel vial that was previously used, go to STEP 3: Preparing Additional Doses from a Single Enbrel Vial.

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.

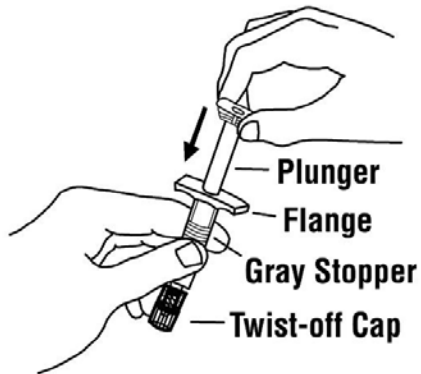


2. Place the Enbrel vial on your flat work surface. Use one alcohol swab to clean the gray stopper on the Enbrel vial. **Do NOT** touch the gray stopper with your hands.
3. Open the wrapper that contains the 25-gauge needle by peeling apart the tabs and set the needle aside for later use. The 25-gauge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

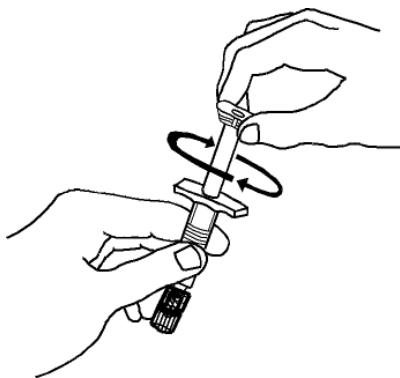
25-Gauge Needle



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

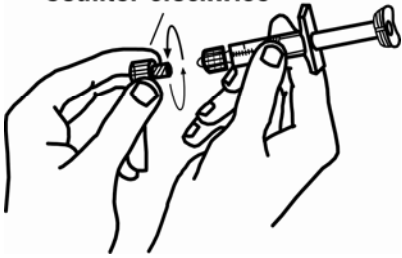


5. Attach the plunger to the gray rubber stopper in the syringe by turning the plunger clockwise until a slight resistance is felt.

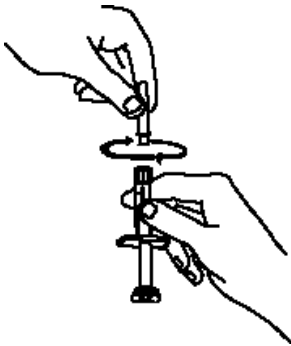


6. Remove the twist-off cap from the prefilled diluent syringe by turning counter-clockwise. **Do NOT** touch or bump the plunger. Doing so could cause the liquid to leak out. You may see a drop of liquid when removing the cap. This is normal. Place the cap on your flat work surface. **Do NOT** touch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

Turn Twist-off Cap
Counter-clockwise

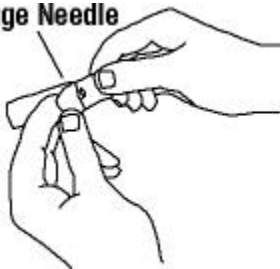


7. Continue to hold the barrel of the syringe. With your free hand, twist the 25-gauge needle onto the tip of the syringe until it fits snugly. Place the syringe on your flat work surface.

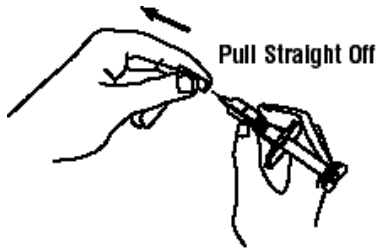


8. Open the wrapper that contains the 27-gauge needle by peeling apart the tabs and set the needle aside for later use. The 27-gauge needle will be used to inject the dose.

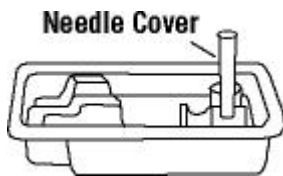
27-Gauge Needle



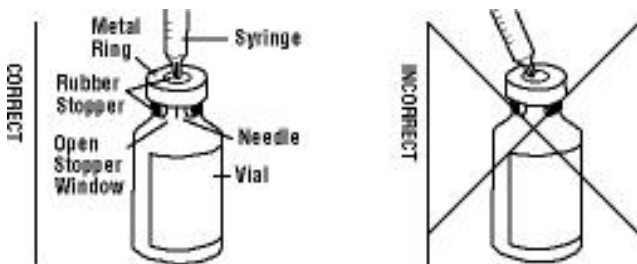
9. Pick up the syringe from your flat work surface. Hold the barrel of the syringe with one hand, and pull the needle cover straight off. To avoid damaging the needle, **do NOT** twist or bend the needle cover while you are removing it. **Do NOT** touch the needle or allow it to touch any surface. **Do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



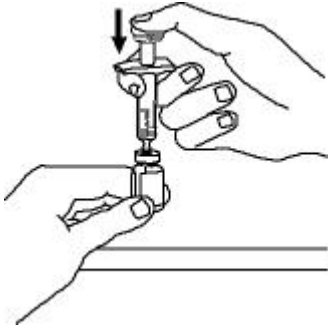
- Place the needle cover (open side up) in the round space marked "N" in the Enbrel dose tray.



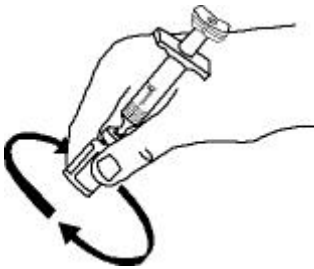
- Place the Enbrel vial on your flat work surface. Hold the syringe with the needle facing up, and gently pull back on the plunger to pull a small amount of air into the syringe. Then, insert the needle straight down through the center ring of the gray stopper (see illustrations). You should feel a slight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



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

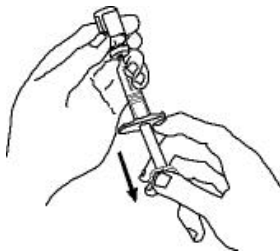


13. Leave the syringe in place. Gently swirl the Enbrel vial in a circular motion to dissolve the powder.

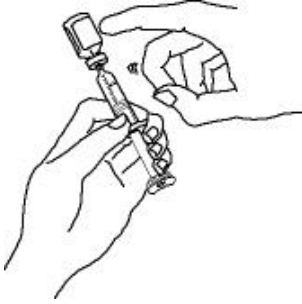


DO NOT SHAKE. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colorless. After the powder has completely dissolved, foam (bubbles) may still be present. This is normal. **Do NOT inject the solution if it is discolored, contains lumps, flakes, or particles.**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

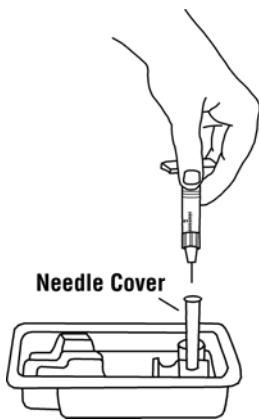
14. With the needle in the Enbrel vial, turn the vial upside down. Hold the syringe at eye level and slowly pull the plunger down to the unit markings on the side of the syringe that correspond with the correct dose. Make sure to keep the tip of the needle in the solution. Some white foam may remain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



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

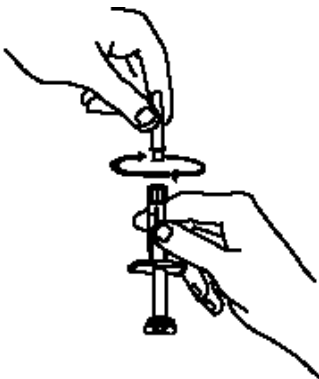


16. Remove the syringe and needle from the Enbrel vial. Keep the needle attached to the syringe and insert the 25-gauge needle straight down into the needle cover in the Enbrel dose tray.



You should hear a “snap” when the needle is secure in the needle cover. Once the needle is secure in the needle cover, untwist the 25-gauge needle from the syringe and dispose of the needle in your sharps disposal container.

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, 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

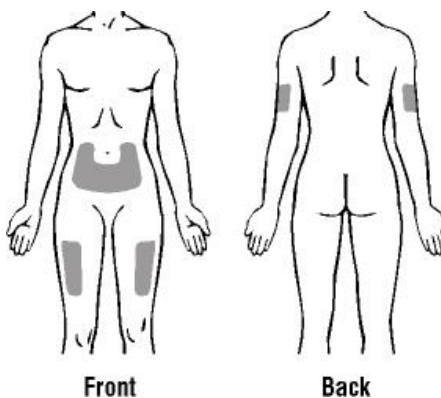
1. Select a clean, well-lit, flat work surface, such as a table.
2. The needles and syringes supplied with Enbrel should not be reused. You will need new ones for each additional dose. Your healthcare provider will tell you what type of syringes (1 mL) and needles (25- and 27-gauge) to use. Place the 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.
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. Three recommended injection sites for Enbrel include: (1) the front of the middle thighs; (2) the abdomen, except for the two-inch area right around the navel; and, (3) the outer area of the upper arms.



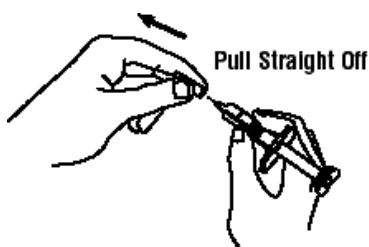
2. Rotate the site for each injection. **Do NOT** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.

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, "dart-like" motion, push the needle 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 doctor 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 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.

Dispose of both the used needle and syringe as instructed by your healthcare provider, or by following these steps:

- **Do NOT** throw the used needle or syringe in the household trash or recycle.
- Place the used needle and syringe in a hard plastic disposal container with a screw-on cap or a metal container with a plastic lid, such as a coffee can, labeled "used syringes." If a metal container is used, cut a small hole in the plastic lid and tape the lid to the metal container. If a hard plastic container is used, always screw the cap on tightly after each use. **Do NOT** use glass or clear plastic containers. Sharps disposal containers may also be purchased at your local pharmacy.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- You should always check first with your healthcare provider for instructions on how to properly dispose of a filled disposal container. There may be special state and local laws for disposing of used needles and syringes. **Do NOT throw the disposal container in household trash. Do NOT recycle.**
- **Always** keep the container out of the reach of children.

- The Enbrel vials, vial adapters, and used alcohol swabs should be placed in the trash. The dose tray and cover may be recycled.

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.

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



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Marketed by Amgen Inc.

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