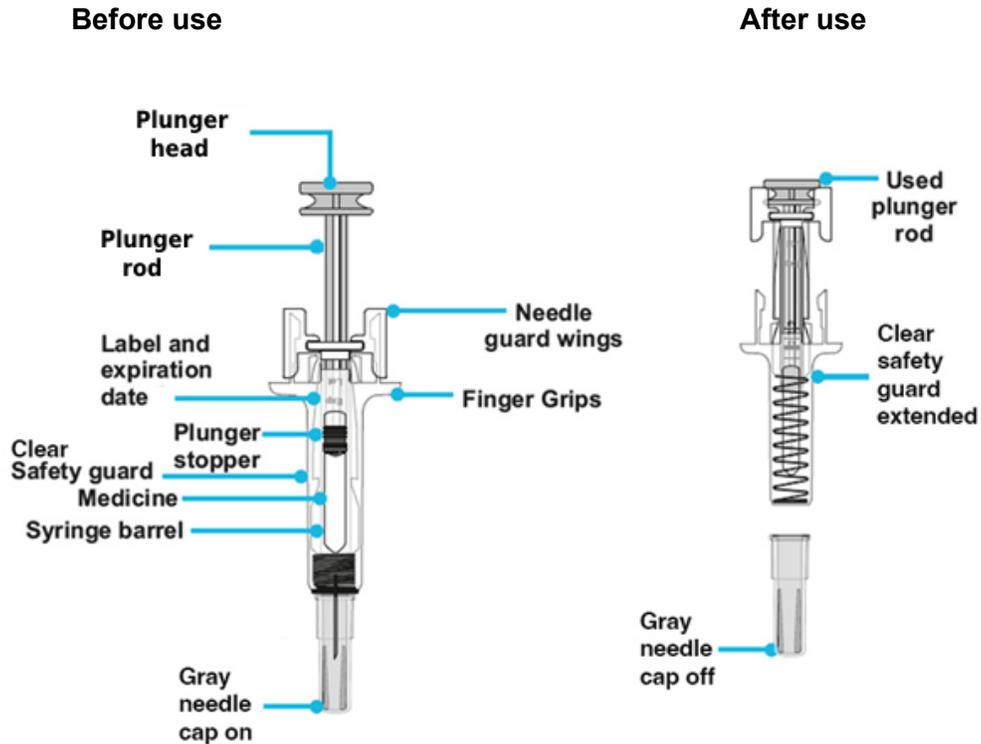


Instructions for Use
FYLNETRA® (fil-ne-trah)
(pegfilgrastim-pbbk)
Injection, for subcutaneous use
Single-Dose Prefilled Syringe

Guide to parts



Important: The needle is covered by the gray needle cap before use.

Important

Read the Patient Information for important information you need to know about FYLNETRA before using these Instructions for Use.

Before you use a FYLNETRA prefilled syringe, read this important information.

Storing the prefilled syringe

- Store FYLNETRA in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze.
- Keep the prefilled syringe in the original pack to protect from light or physical damage.
- Take the prefilled syringe out of the refrigerator 30 minutes before use and allow it to reach room temperature before preparing an injection.
- Throw away (dispose of) any FYLNETRA that has been at left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 72 hours.
- Keep the FYLNETRA prefilled syringe out of the reach of children.

Using the prefilled syringe

- **It is important that you do not try to give the injection unless you or your caregiver has received training from your healthcare provider.**
- Make sure the name FYLNETRA appears on the pack and prefilled syringe label.
- Check the pack and prefilled syringe label to make sure the dose strength is 6 mg/0.6 mL.
- You should not inject a dose of FYLNETRA to children weighing less than 45 kg from a FYLNETRA prefilled syringe. A dose less than 0.6 mL (6 mg) cannot be accurately measured using the FYLNETRA prefilled syringe.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** shake the prefilled syringe.
- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if the pack is open or damaged.
- **Do not** use a prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** attempt to activate the needle safety guard prior to injection.

Call your healthcare provider if you or your caregiver have any questions.

Step 1: Prepare

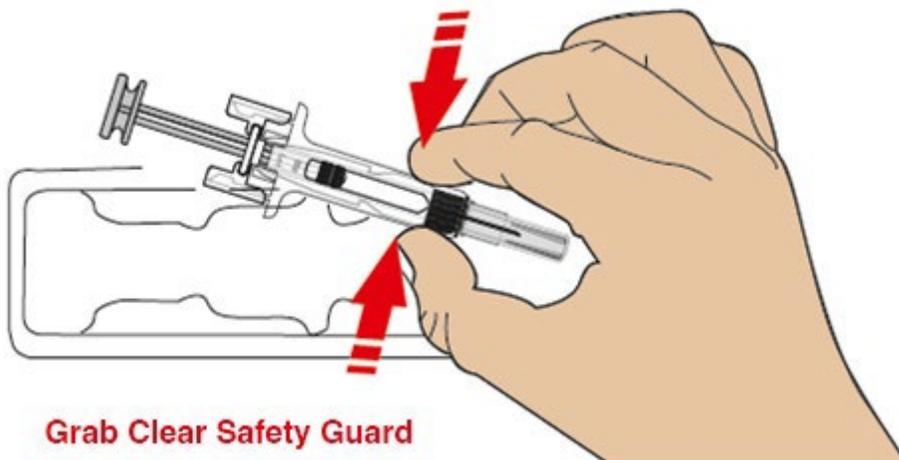
A. Remove the prefilled syringe pack from the refrigerator.

Put the original pack with any unused prefilled syringes back in the refrigerator.

Remove the syringe tray from the pack. On a clean, well-lit surface, place the syringe tray at room temperature for **30** minutes before you give an injection.

- **Do not** use the prefilled syringe if the pack is damaged.
- **Do not** try to warm the prefilled syringe by using a heat source such as hot water or microwave.
- **Do not** leave the prefilled syringe in direct sunlight.
- **Do not** shake the prefilled syringe.

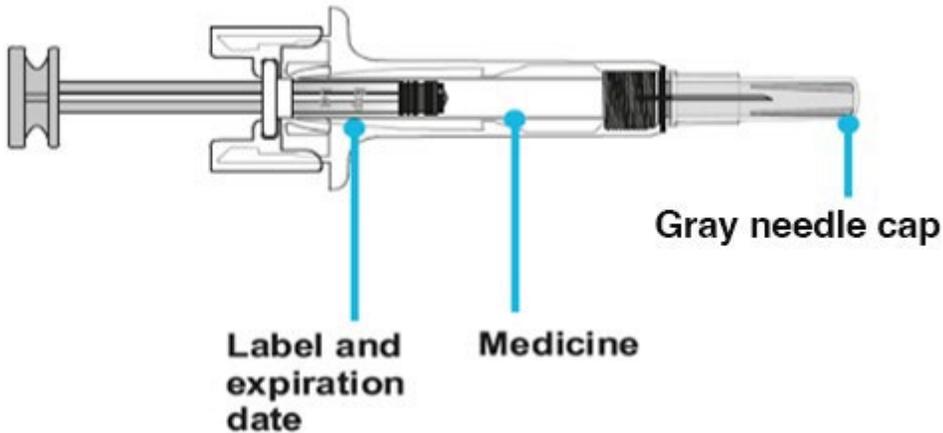
Open the tray by peeling away the cover. Grab the clear safety guard to remove the prefilled syringe from the tray.



For safety reasons:

- **Do not** grab the plunger rod.
- **Do not** grab the gray needle cap.

B. Inspect the medicine and prefilled syringe.



Make sure the medicine in the prefilled syringe is clear and colorless.

- **Do not** use the prefilled syringe if:
 - The medicine is cloudy or discolored, or contains flakes or particles
 - Any part appears cracked or broken
 - The prefilled syringe has been dropped
 - The gray needle cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

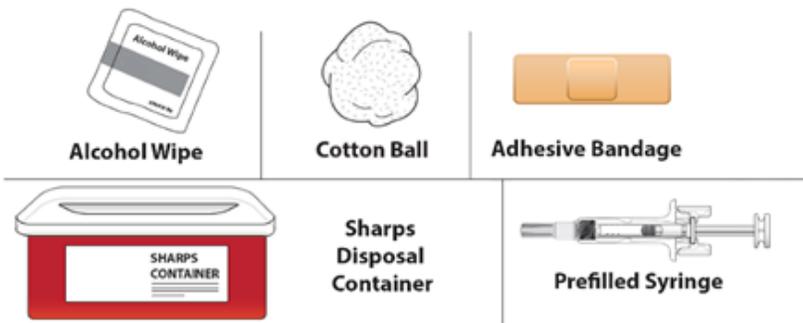
In all cases, use a new prefilled syringe and call your healthcare provider.

C Gather all materials needed for the injection.

Wash your hands thoroughly with soap and water.

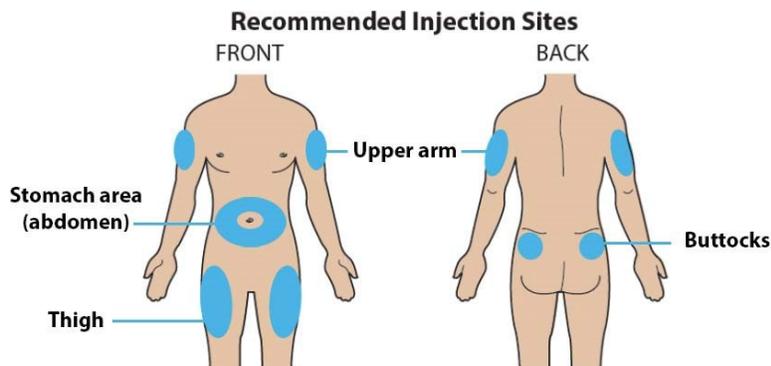
On a clean, well-lit work surface place the:

- Prefilled syringe
- Alcohol wipe
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



Step 2: Get ready

D Prepare and clean the injection site(s).



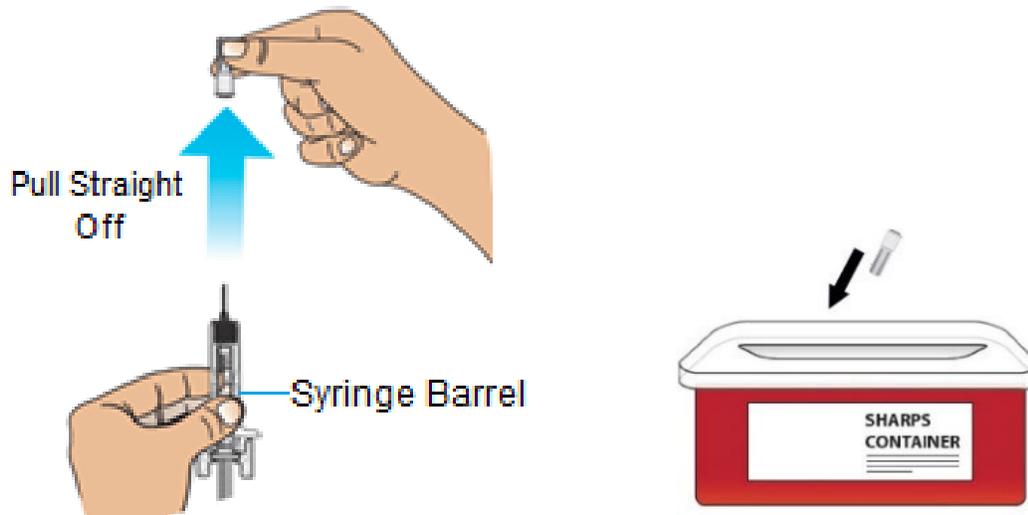
You can use:

- Thigh
- Stomach area (abdomen), except for a 2-inch area around the navel (belly button)
- Upper outer area of the buttocks (only if someone else is giving you the injection)
- Outer area of upper arm (only if someone else is giving you the injection)

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

- **Do not** touch this area again before injecting.
- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

E Hold the prefilled syringe by the barrel. Carefully pull the gray needle cap straight off and away from the body.



- **Do not** remove the gray needle cap from the prefilled syringe until you are ready to inject.
- **Do not** twist or bend the gray needle cap.
- **Do not** hold the prefilled syringe by the plunger rod.
- **Do not** put the gray needle cap back onto the prefilled syringe.

Important: Throw the gray needle cap into the sharps disposal container.

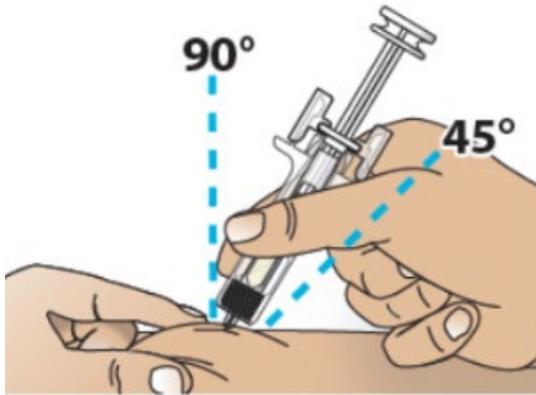
Step 3: Subcutaneous (under the skin) injection

F Pinch the injection site to create a firm surface.

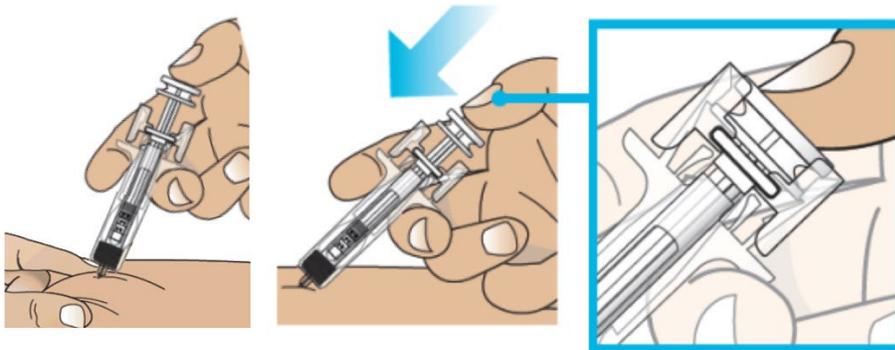


Important: Keep skin pinched while injecting.

G Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



H Using slow and constant pressure, push the plunger rod until it reaches the bottom and the plunger head is completely between the needle guard wings.



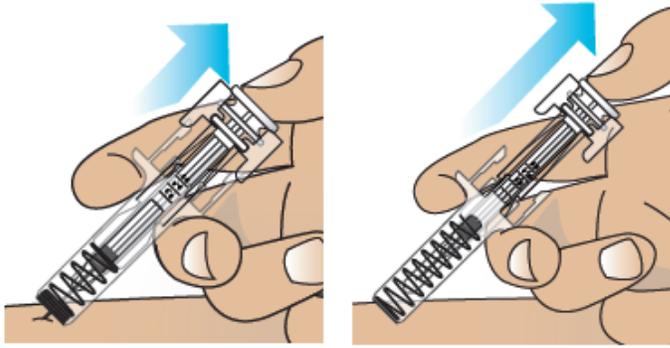
Important: When you remove the syringe, if it looks like the medicine is still in the syringe barrel, this means you have not received a full dose. Call your healthcare provider right away.

Step 4: Finish



I **Before you finish!**

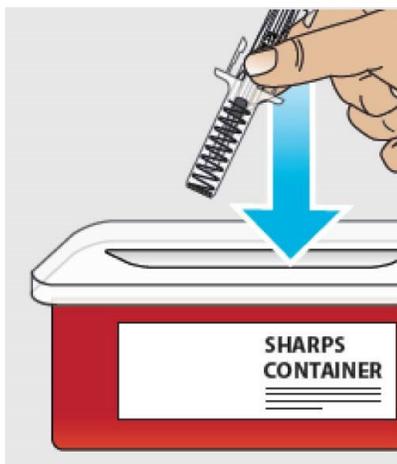
- While you continue to hold the syringe, slowly let go of the plunger head.
- As you let go of the plunger head, the needle will automatically slide into the clear safety guard until the needle is completely covered.



Important: If the clear safety guard does not activate after Step I, remove the needle from the skin and throw away (discard of) the used prefilled syringe as instructed in Step J right away.

Keep your hands away from the needle at all times.

J Discard (throw away) the used prefilled syringe



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

- **Do not** recycle the prefilled syringe or sharps disposal container or throw them into the household trash.

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

K Examine the injection site.

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

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

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