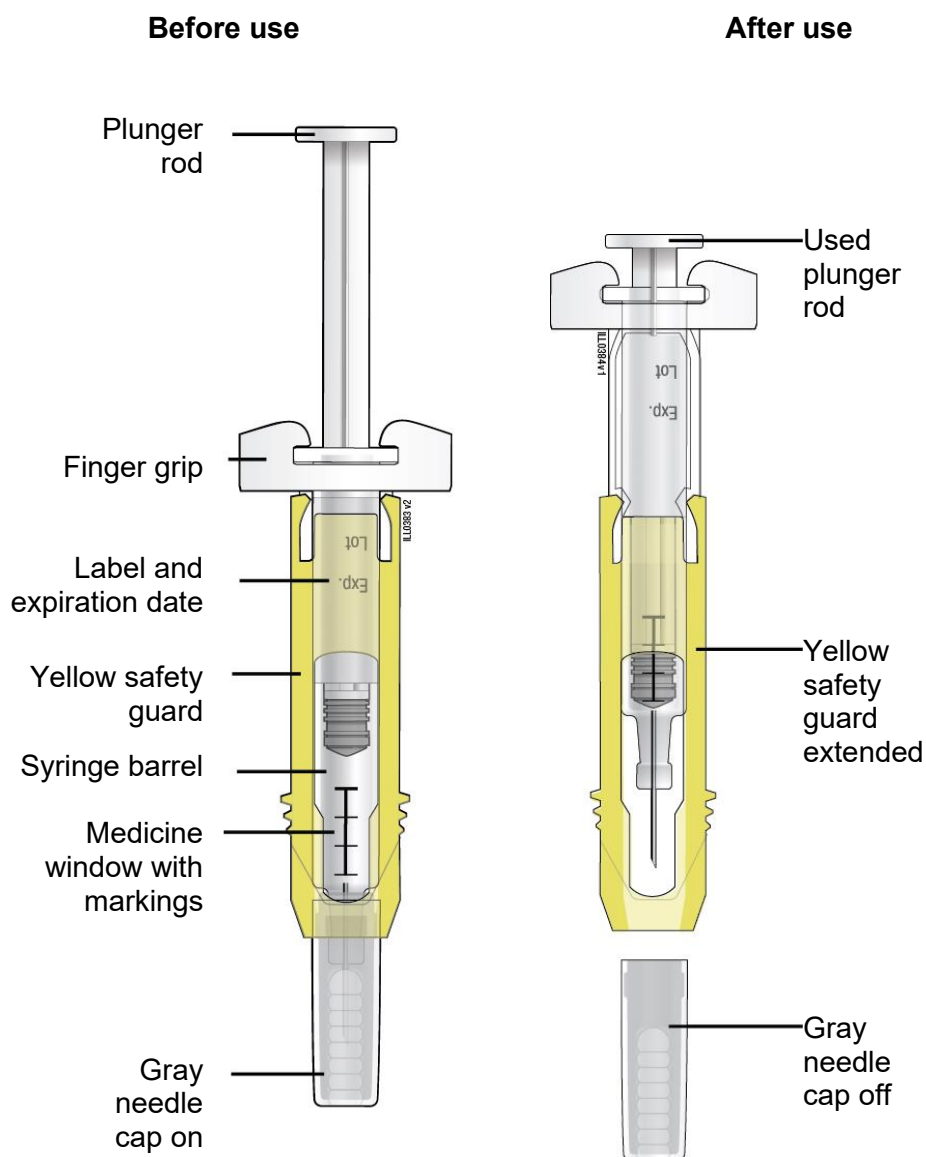


Instructions for Use
ARANESP® (Air-uh-nesp)
(darbepoetin alfa)
Injection
Single-Dose Prefilled Syringe (SingleJect®)

Guide to parts



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

Important

Read the Medication Guide for important information you need to know about Aranesp before using these Instructions for Use.

Before you use an Aranesp prefilled syringe, read this important information

Storing your prefilled syringe

- Keep the prefilled syringe in the original carton to protect from light or physical damage.
- Store the prefilled syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** use a prefilled syringe that has been frozen.
- After you inject your dose, throw away (dispose of) any unused Aranesp left in the prefilled syringe. **Do not** save unused Aranesp in the prefilled syringe for later use.
- Keep the Aranesp prefilled syringe out of the reach of children.

Using your 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 Aranesp appears on the carton and prefilled syringe label.
- **Do not** use a prefilled syringe after the expiration date on the label.
- **Do not** use a prefilled syringe that has been shaken.
- **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** slide the yellow safety guard over the needle before you give the injection. This will “activate” or lock the yellow safety guard. Use another prefilled syringe that has not been activated and is ready to use.
- The gray needle cap on the prefilled syringe contains dry natural rubber (made from latex). **Tell your healthcare provider if you are allergic to latex.**

Call your healthcare provider if you have any questions.

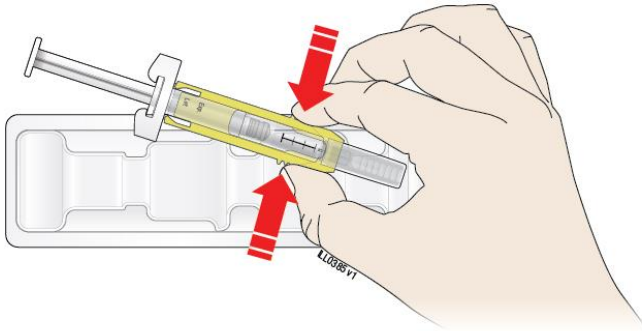
Step 1: Prepare

A Remove one prefilled syringe from the refrigerator.

The original pack with any unused prefilled syringes should remain in the refrigerator.

- **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 package and remove the syringe from the tray. Grab the yellow safety guard to remove the prefilled syringe from the tray.

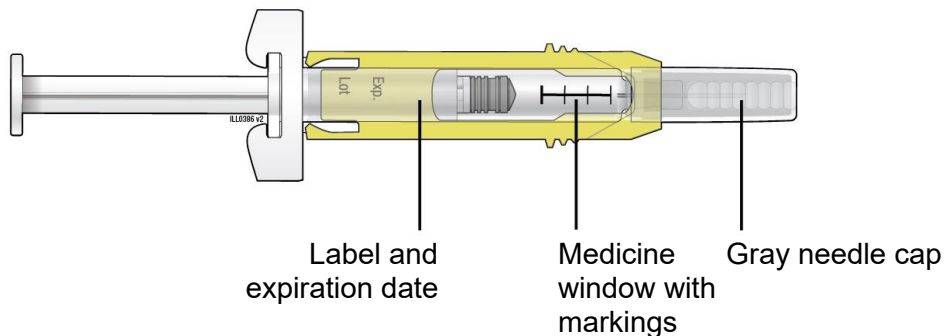


Grab Yellow Safety Guard

For safety reasons:

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

B Inspect the medicine and prefilled syringe.



Turn the prefilled syringe so you can see the medicine window and markings. 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.

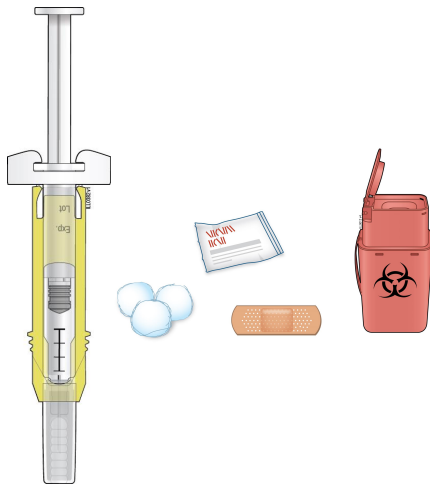
In all cases, use a new prefilled syringe and call your healthcare provider.

C Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.

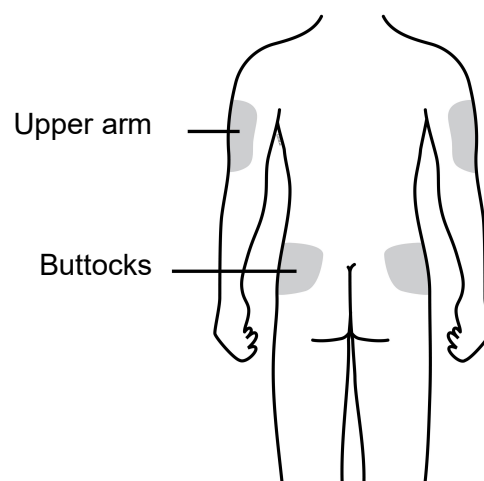
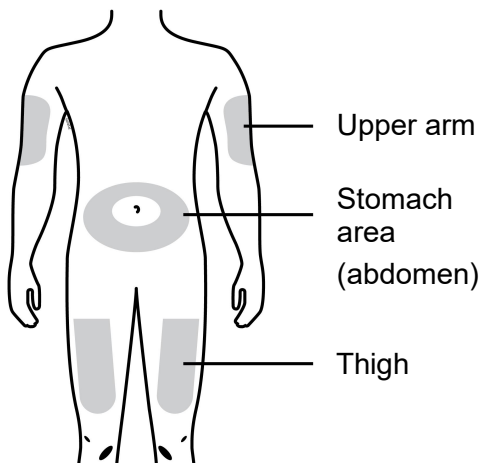
On a clean, well-lit work surface, place the:

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



Step 2: Get ready

D Prepare and clean your injection site(s).



You can use:

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

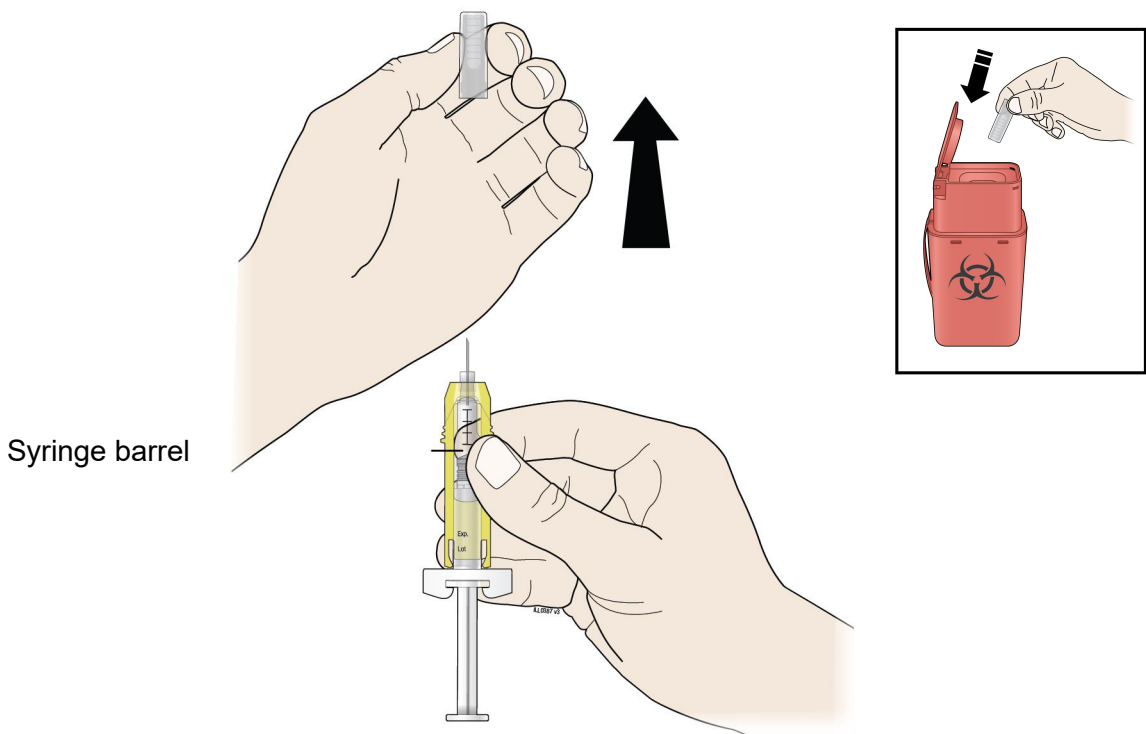
- Outer area of upper arm (only if someone else is giving you the injection)

Clean your injection site with an alcohol wipe. Let your 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 area 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.

Important: Follow your healthcare provider's instructions about selecting sites for injection appropriate to you and about changing the site for each injection.

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

F

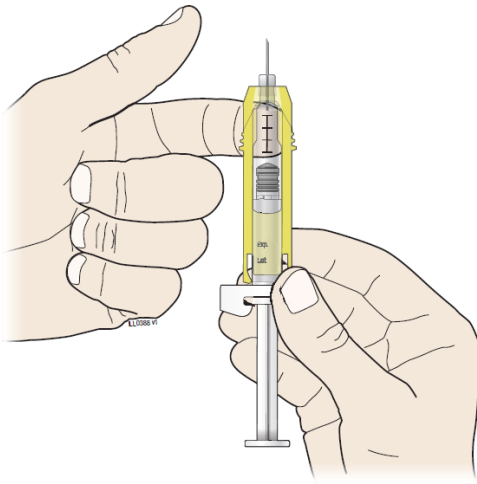


Check your prescription before you inject your dose.

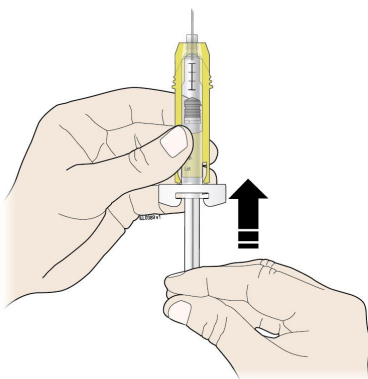
Your healthcare provider has prescribed either a “full” syringe dose or a “partial” syringe dose of Aranesp.

- If you are prescribed a full dose of Aranesp, you will inject all of the medicine from your prefilled syringe. **For a full dose, go directly to Step 3**, and choose between the Subcutaneous or Port injection based on your healthcare provider’s instructions.
- **If you are prescribed a partial dose of Aranesp, start with Step G below.**

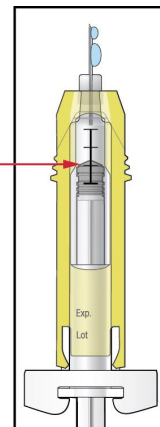
G Point the needle up and tap gently until the air rises to the top.



H Slowly push the plunger rod up to the line on the syringe barrel that matches your prescribed dose.



Plunger to
prescribed
dose



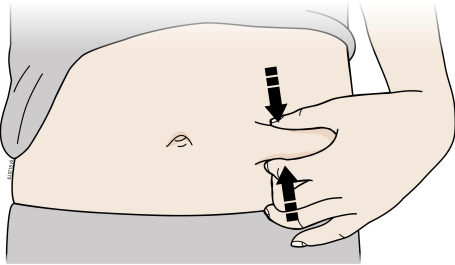
Important: Do not slide the yellow safety guard over the needle before you give the injection. This will “activate” or lock the yellow safety guard.

As you push the plunger rod up, air and extra medication is removed. Check to make sure the plunger lines up with the syringe marking for your prescribed dose. If you remove too much medication, get a new prefilled syringe and start again at **Step 1**.

Call your healthcare provider if you have problems measuring your prescribed dose.

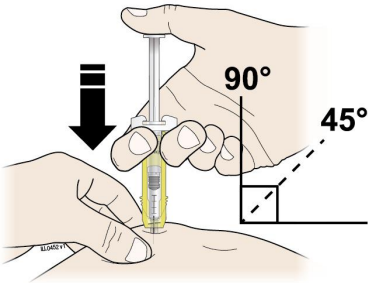
Step 3: Subcutaneous (under the skin) injection

I Pinch your injection site to create a firm surface.



Important: Keep skin pinched while injecting.

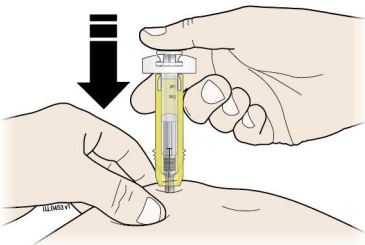
J Hold the pinch. Insert the needle into the skin at 45 to 90 degrees.



K Using slow and constant pressure, push the plunger rod until it reaches the bottom.

- Do not pull back the plunger rod while the needle is inserted.

When done, gently pull the syringe off of your skin, and **continue to Step 4: Finish.**



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.

..... **OR**

Step 3: Port Injection

If your healthcare provider has prescribed injection into your home hemodialysis system, you should be first trained by your healthcare provider and then follow the procedure described below.

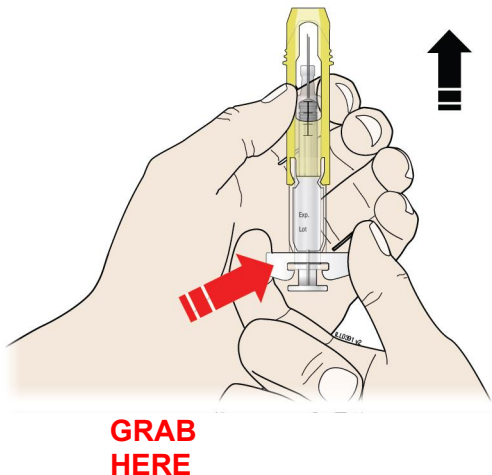
- A. Locate the port on the hemodialysis tubing where your healthcare professional prescribed you to inject. **Do not** inject into the hemodialysis tubing.
- B. Clean the port with an alcohol wipe.
- C. Insert the prefilled syringe needle at a 90° angle, directly into the center of the rubber septum located on the cleaned port. **Do not** bend the needle. The rubber septum may require increased pressure to penetrate with the needle.
- D. Push the plunger down until it reaches the bottom.
- E. Remove the prefilled syringe from the port.

Now, continue to Step 4: Finish.

Step 4: Finish



For your safety, pull the yellow safety guard until it clicks and covers the needle.



Once extended, the yellow safety guard will lock into position and will not slide back over the needle.

Keep your hands away from the needle at all times.

M Discard (throw away) the used prefilled syringe.



- Put the used syringe in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of)** the prefilled syringe in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, 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 syringe or sharps disposal container or throw them into household trash.

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

N Examine the injection site.

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

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



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