

Instructions for Use
ARANESP® (Air-uh-nesp)
(darbepoetin alfa)

Single-Dose Vial

Use these Instructions for Use if you or your caregiver has been trained to give Aranesp injections at home. Do not give yourself the injection unless you have received training from your healthcare provider. If you are not sure about giving the injection or if you have questions, ask your healthcare provider for help.

Before reading these Instructions for Use, read the Medication Guide that comes with Aranesp for the most important information you need to know.

When you receive your Aranesp vial and syringes make sure that:

- The name Aranesp appears on the carton and vial label.
- The expiration date on the vial label has not passed. Do not use a vial of Aranesp after the expiration date on the label.
- The dose strength of the Aranesp vial (number of micrograms [mcg] in the colored square on the package and on the vial label) is the same as your healthcare provider prescribed.
- The Aranesp liquid in the vial is clear and colorless. Do not use Aranesp if the liquid in the vial looks discolored or cloudy, or if the liquid has lumps, flakes, or particles.
- The Aranesp vial has a color cap on the top of the vial. Do not use a vial of Aranesp if the color cap on the top of the vial has been removed or is missing.
- Use only the type of disposable syringe and needle that your healthcare provider has prescribed.
- Do not shake Aranesp. Shaking could cause Aranesp not to work. If you shake Aranesp, the solution in the vial may look foamy and should not be used.
- Do not freeze Aranesp. Do not use a vial of Aranesp that has been frozen.
- Store Aranesp in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep Aranesp away from light.

- Single-dose vials of Aranesp should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

How should I prepare for an injection of Aranesp?

- Always keep an extra syringe and needle on hand.
- Follow your healthcare provider's instructions on how to measure your dose of Aranesp. This dose will be measured in milliliter (mL) or cc (1 mL is the same as 1 cc). Use a syringe that is marked in tenths of mL (for example, 0.2 mL or 0.2 cc). Using the wrong syringe can lead to a mistake in your dose and you could inject too much or too little Aranesp.

Only use disposable syringes and needles. Use the syringes and needles only one time and then throw them away as instructed by your healthcare provider.

Important: Follow these instructions exactly to help avoid infections.

Preparing the dose:

1. Remove the vial of Aranesp from the refrigerator. During this time, protect the solution from light. Keep the vial in its carton until you are ready to prepare the dose. Do not leave the vial in light.
2. Do not use a single-dose vial of Aranesp more than one time.
3. **Do not shake Aranesp.**

4. Gather the other supplies you will need for your injection (vial, syringe, alcohol wipes, cotton ball, and a puncture-proof container for throwing away the syringe and needle). See Figure 1.

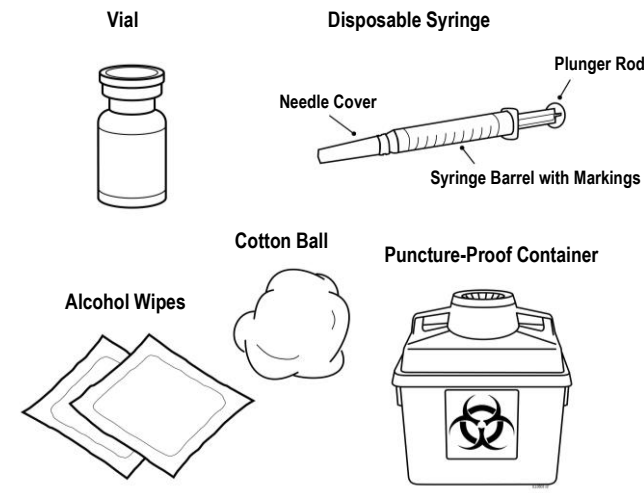


Figure 1

5. Check the date on the Aranesp vial to be sure that the drug has not expired.
6. Wash your hands well with soap and water before preparing the medicine. See Figure 2.



Figure 2

7. Flip off the protective color cap on the top of the vial. Do not remove the grey rubber stopper. Wipe the top of the grey rubber stopper with an alcohol wipe. See Figures 3 and 4.

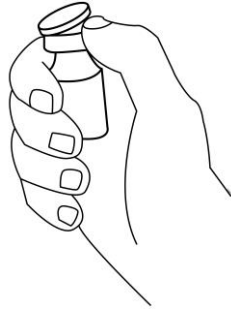


Figure 3

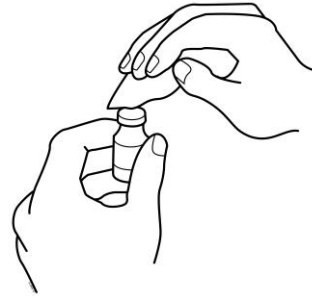


Figure 4

8. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Throw away the syringe in the puncture-proof disposable container. If the syringe package is undamaged, open the package and remove the syringe.
9. Using a syringe and needle that has been recommended by your healthcare provider, carefully remove the needle cover. See Figure 5. Then draw air into the syringe by pulling back on the plunger. The amount of air drawn into the syringe should be equal to the amount (mL or cc) of the Aranesp dose prescribed by your healthcare provider. See Figure 6.

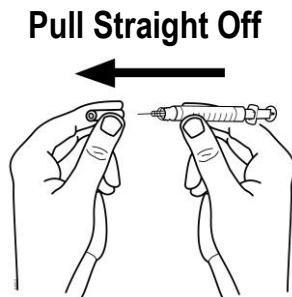


Figure 5

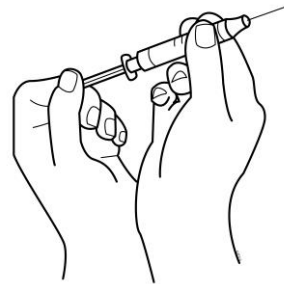


Figure 6

10. With the vial on a flat work surface, insert the needle straight down through the grey rubber stopper of the Aranesp vial. See Figure 7.
11. Push the plunger of the syringe down to inject the air from the syringe into the vial of Aranesp. The air injected into the vial will allow Aranesp to be easily withdrawn into the syringe. See Figure 7.

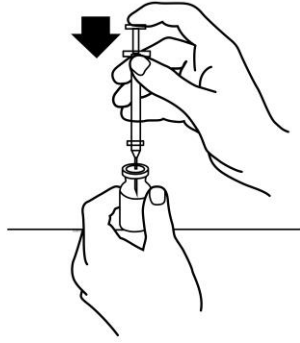


Figure 7

12. Keep the needle inside the vial. Turn the vial and syringe upside down. Be sure the tip of the needle is in the Aranesp liquid. Keep the vial upside down. Slowly pull back on the plunger to fill the syringe with Aranesp liquid to the number (mL or cc) that matches the dose your healthcare provider prescribed. See Figure 8.

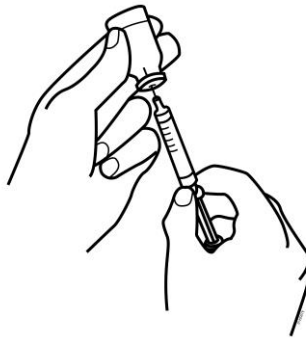


Figure 8

13. Keep the needle in the vial. Check for air bubbles in the syringe. A small amount of air is harmless. Too large an air bubble will give you the wrong Aranesp dose. To remove air bubbles, gently tap the syringe with your fingers 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. Keep the tip of the needle in the Aranesp liquid. Pull the plunger back to the number on the syringe that matches your dose. Check again for air bubbles. If there are still air bubbles, repeat the steps above to remove them. See Figures 9 and 10.

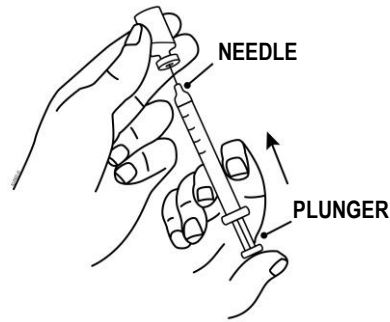


Figure 9

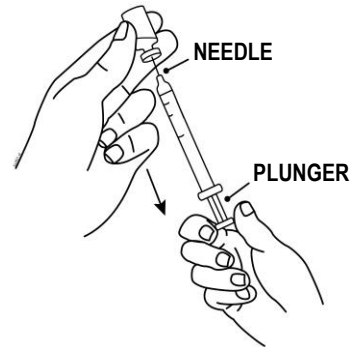


Figure 10

14. Double-check that you have the correct dose in the syringe. Lay the vial down on its side with the needle still in it until after you have selected and prepared a site for injection.

Selecting and preparing the injection site:

Aranesp can be injected into your body using two different ways (routes) as described below. Follow your healthcare provider's instructions about how you should inject Aranesp. For patients on hemodialysis, the intravenous (IV) route is recommended.

1. Subcutaneous Route:

- Aranesp can be injected directly into a layer of fat under your skin. This is called a subcutaneous injection. When giving subcutaneous injections, follow your healthcare provider's instructions about changing the site for each injection. You may wish to write down the site where you have injected.
- Do not inject Aranesp into an area that is tender, red, bruised, hard, or has scars or stretch marks. Recommended sites for injection are shown in Figure 11 below, including:
 - The outer area of the upper arms
 - The abdomen (except for the 2-inch area around the navel)
 - The front of the middle thighs
 - The upper outer area of the buttocks

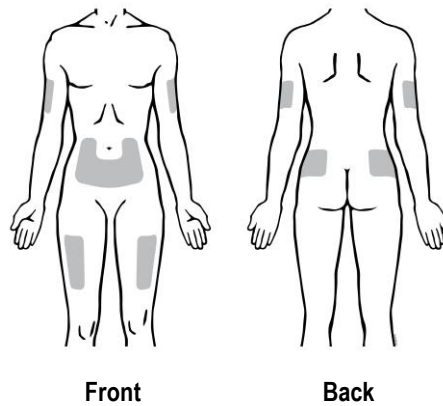


Figure 11

- Clean the skin with an alcohol wipe where the injection is to be made. Be careful not to touch the skin that has been wiped clean. See Figure 12.

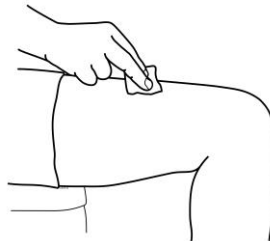


Figure 12

- Double-check that the correct amount of Aranesp is in the syringe.
- Remove the prepared syringe and needle from the vial of Aranesp and hold it in the hand that you will use to inject the medicine.
- Use the other hand to pinch a fold of skin at the cleaned injection site. Do not touch the cleaned area of skin. See Figure 13.

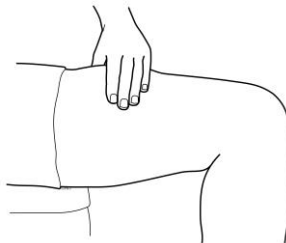


Figure 13

- Hold the syringe like you would hold a pencil. Use a quick “dart-like” motion to insert the needle either straight up and down (90-degree angle) or at a slight angle (45 degrees) into the skin. Inject the prescribed dose

subcutaneously as directed by your doctor, nurse, or pharmacist. See Figure 14.

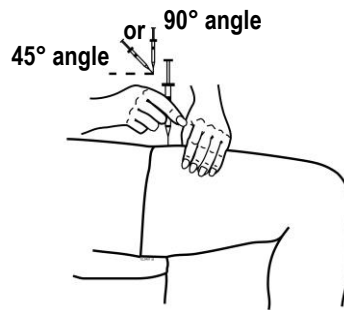


Figure 14

- Pull the needle out of the skin and press a cotton ball or gauze over the injection site and hold it there for several seconds. Do not recap the needle.
- Dispose of the used syringe and needle as described below. Do not reuse syringes and needles.

2. Intravenous Route:

- Aranesp can be injected in your vein through a special access port placed by your healthcare provider. This type of Aranesp injection is called an intravenous (IV) injection. This route is usually for hemodialysis patients.
- If you have a dialysis vascular access, make sure it is working by checking it as your healthcare provider has shown you. Be sure to let your healthcare provider know right away if you are having any problems, or if you have any questions.
- Wipe off the venous port of the hemodialysis tubing with an alcohol wipe. See Figure 15.

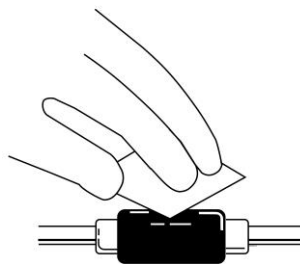


Figure 15

- Insert the needle of the syringe into the cleaned venous port and push the plunger all the way down to inject all the Aranesp. See Figure 16.

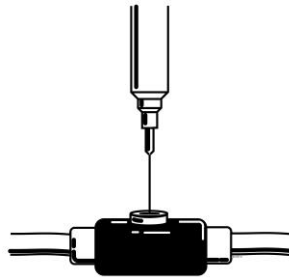


Figure 16

- Remove the syringe from the venous port. Do not recap the needle.
- Dispose of the used syringe and needle as described below.

How should I dispose of the vials, syringes, and needles?

Do not reuse the single-dose vials, syringes, or needles. Throw away the vials, syringes, and needles as instructed by your healthcare provider or by following these steps:

- Do not throw the vials, syringes, or needles in the household trash or recycle.
- Do not put the needle cover back on the needle.
- Place all used needles and syringes in a puncture-proof disposable container with a lid. Do not use glass or clear plastic containers, or any container that will be recycled or returned to a store.
- Keep the puncture-proof disposable container out of the reach of children.
- When the puncture-proof disposable container is full, tape around the cap or lid to make sure the cap or lid does not come off. Throw away the puncture-proof disposable container as instructed by your healthcare provider. There may be special state and local laws for disposing of used needles and syringes. **Do not throw the puncture-proof disposable container in the household trash. Do not recycle.**

Keep Aranesp and all medicines out of the reach of children.

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



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