

Instructions for Use

Aranesp[®] (Air-uh-nesp) (darbepoetin alfa)

Single-Dose Prefilled Syringe (SingleJect[®])

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 prefilled syringe make sure that:

- The name Aranesp appears on the carton and prefilled syringe label.
- The expiration date on the prefilled syringe label has not passed. Do not use a prefilled syringe of Aranesp after the expiration date on the label.
- The dose strength of the Aranesp prefilled syringe (number of micrograms [mcg] in the colored square on the package and on the prefilled syringe label) is the same as your healthcare provider prescribed.
- The Aranesp liquid in the prefilled syringe is clear and colorless. **Do not use Aranesp if the liquid in the prefilled syringe looks discolored or cloudy, or if the liquid has lumps, flakes, or particles.**
- Do not use Aranesp in a prefilled syringe if the grey cover on the needle is off, or the needle guard (clear yellow plastic sleeve on the syringe) has been pulled to extend over the needle (activated).
- **Do not shake Aranesp.** Shaking could cause Aranesp not to work. If you shake Aranesp the solution may look foamy and it should not be used.
- **Do not freeze Aranesp. Do not use an Aranesp prefilled syringe 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.

How should I prepare for an injection of Aranesp?

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 the prefilled syringe only one time and throw it away as instructed by your healthcare provider.

Important: Follow these instructions exactly to help avoid infections.

Preparing the dose:

1. Remove one prefilled syringe from the refrigerator. During this time, protect the prefilled syringe from light. Keep the prefilled syringe in its wrapper until you are ready to prepare your dose. Do not leave the prefilled syringe in light.
2. Use each Aranesp prefilled syringe only one time.
3. Do not shake Aranesp.
4. Gather the other supplies you will need for your injection (prefilled syringe with a clear yellow plastic needle guard attached, alcohol wipes, cotton ball, and a puncture-proof container for throwing away the prefilled syringe). See Figure 1.

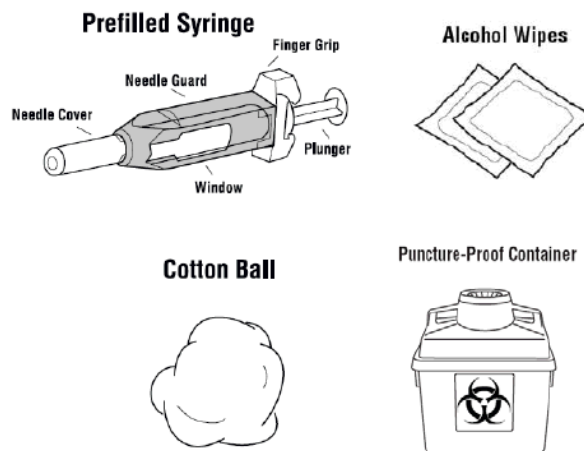


Figure 1

5. Check the date on the label on your Aranesp prefilled syringe 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. Open the package and remove the syringe from the tray. Check to see that the needle cover is on and the yellow needle guard is covering the barrel of the syringe. If the needle guard is covering the needle, then it has already been activated. **Do not** use that syringe. Throw away the syringe in the puncture-proof disposable container. Use a new syringe. **Do not** slide the needle guard over the needle cover before injection. This will “activate” or lock the needle guard.
8. Hold the syringe with the needle pointing up to prevent the Aranesp from leaking out of the needle. Carefully pull the needle cover straight off. See Figure 3.

Pull Straight Off

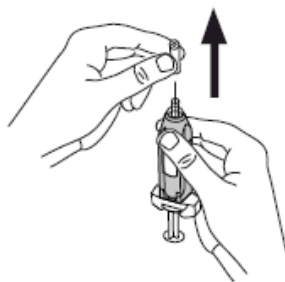


Figure 3

9. Check the syringe for air bubbles. If there are 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. See Figure 4.

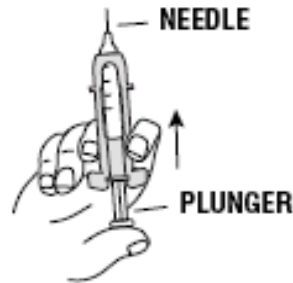


Figure 4

10. Keep holding the syringe up. Slowly push the plunger to the line on the syringe that matches the dose your healthcare provider has prescribed.
11. Check again to make sure that you have the correct dose in the syringe.
12. When you put the syringe down on your work surface, be careful not to let the needle touch anything.

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 5 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 your buttocks

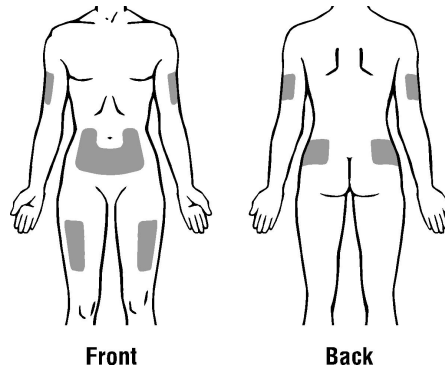


Figure 5

- 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 6.



Figure 6

- Hold the prefilled syringe 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 7. Note: Hold the syringe barrel through the two needle guard windows when giving the injection.

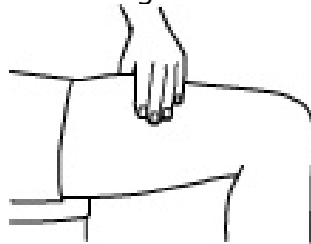


Figure 7

- 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 8.

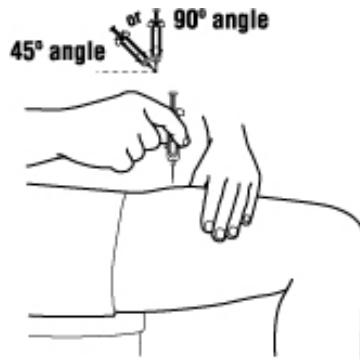


Figure 8

- 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 prefilled syringe as described below. Do not reuse the prefilled syringe.

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 9.

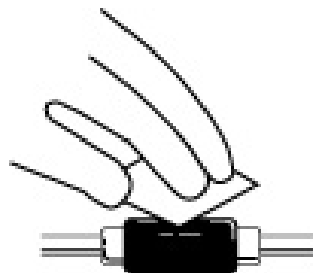


Figure 9

- Insert the needle of the prefilled syringe into the cleaned venous port and push the plunger all the way down to inject all the Aranesp. See Figure 10.

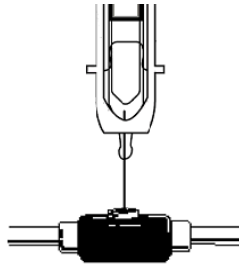


Figure 10

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

Activation of the needle guard on used prefilled syringes

After injecting Aranesp from the prefilled syringe, do not recap the needle. Keep your hands behind the needle at all times. To activate the needle guard, hold the finger grip of the syringe with one hand and grasp the needle guard with your free hand. Slide the needle guard completely over the needle until the needle guard clicks into place. See Figures 11 and 12. **NOTE: If you do not hear a click, the needle guard may not be completely activated.**

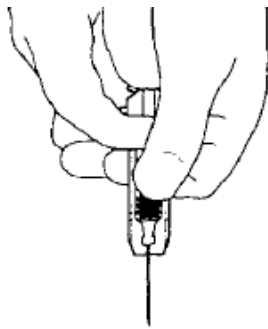


Figure 11

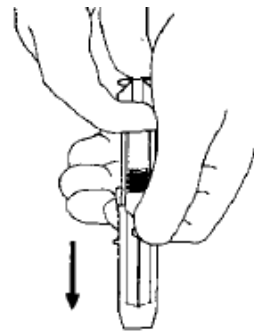


Figure 12

How should I dispose of the prefilled syringe?

Do not reuse the prefilled syringe. Throw away the prefilled syringe with the activated needle guard as directed by your healthcare provider or by following these steps:

- Do not throw the prefilled syringes in the household trash or recycle.
- Do not put the needle cover back on the needle.

- Place the used prefilled syringe 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 prefilled syringes.
Do not throw the puncture-proof disposable container in the household trash. Do not recycle.

Keep Aranesp and all medicines out of reach of children.

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

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