

FDA Approved: 11-8-07

**Patient Information**

**Aranesp<sup>®</sup> (Air-uh-nesp)**

**darbepoetin alfa**

***Single-dose Vial/ Single-dose Prefilled Syringe (SingleJect<sup>®</sup>)***

This patient package insert contains information and directions for patients (and their caregivers) whose doctor has determined that they may receive injections of Aranesp<sup>®</sup> (Air-uh-nesp) at home. Please read it carefully. This patient package insert does not include all information about Aranesp<sup>®</sup> and does not replace talking with your doctor. You should discuss any questions about treatment with Aranesp<sup>®</sup> with your doctor. Only your doctor can prescribe Aranesp<sup>®</sup> and determine if it is right for you.

**What is the most important information I should know about Aranesp<sup>®</sup>?**

Aranesp<sup>®</sup> can cause serious side effects:

Chronic kidney failure patients:

- If your hemoglobin is kept too high, you have an increased chance of heart attack, stroke, heart failure, blood clots, and death. Your doctor should try to keep your hemoglobin between 10 and 12 g/dL.

Cancer patients:

- You may have an increased chance of dying sooner or your tumor (cancer) may grow faster if you take this drug.
- Your doctor should use the lowest dose of Aranesp<sup>®</sup> needed to help you avoid red blood cell transfusions.
- Once you have completed your chemotherapy course, Aranesp<sup>®</sup> treatment should be stopped.

All patients:

- Aranesp<sup>®</sup> treatment increases your chance of a blood clot. If you are scheduled for surgery, your doctor may prescribe a blood thinner to prevent blood clots.
- Blood clots can form at your vascular access if you are receiving hemodialysis. Call your doctor or dialysis center if you think your access is blocked.

- Blood clots can form in blood vessels (veins) in your leg (venous thrombosis). Blood clots may move from the legs to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your doctor right away if you experience any of the following symptoms of a blood clot, while taking Aranesp<sup>®</sup>:

- chest pain
- shortness of breath
- pain in the legs with or without swelling

You will be asked to have blood tests that will check the number of red blood cells your body is producing. The blood tests will see if Aranesp<sup>®</sup> is working and if your hemoglobin level is getting too high. Your doctor may refer to the results of your blood tests as hemoglobin and hematocrit. The amount of time it takes to reach the red blood cell level that is right for you, and the dose of Aranesp<sup>®</sup> needed to make the red blood cell level rise, is different for each person. You may need Aranesp<sup>®</sup> dose adjustments before you reach your correct dose of Aranesp<sup>®</sup> and the correct dose may change over time. It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of Aranesp<sup>®</sup> as needed.

Please also read “**What are the possible side effects of Aranesp<sup>®</sup>?**” below.

### **What is Aranesp<sup>®</sup>?**

Aranesp<sup>®</sup> is a man-made form of the protein human erythropoietin (ee-rith-row-po-eh-tin). Aranesp<sup>®</sup> works by stimulating your bone marrow to make red blood cells. After two to six weeks of treatment, your red blood cell counts may increase.

Aranesp<sup>®</sup> may be used to treat your anemia (a lower than normal number of red blood cells) if it is caused by:

- chronic kidney failure (you may or may not be on dialysis)
- chemotherapy used to treat cancer

Aranesp<sup>®</sup> does not improve symptoms of anemia, quality of life, or patient well-being for patients with cancer.

Before receiving Aranesp<sup>®</sup>, you should talk with your doctor about the benefits and risks of Aranesp<sup>®</sup>.

## **Who should not take Aranesp<sup>®</sup>?**

**You should not take Aranesp<sup>®</sup> if you have:**

- High blood pressure that is not controlled (uncontrolled hypertension).
- Antibodies to Aranesp<sup>®</sup> or other erythropoietins.

**Talk to your doctor** if you are not sure if you have these conditions or if you have any questions about this information.

## **What should I tell my doctor before taking Aranesp<sup>®</sup>?**

Tell your doctor about all your health conditions and all the medicines you take, including prescription and over-the-counter medicines, vitamins, supplements, and herbals. Be sure to tell your doctor if you have:

- Heart disease
- High blood pressure
- Any history of seizures or strokes
- Blood disorders (such as sickle cell anemia, blood clotting disorders)

Tell your doctor if you are:

- Pregnant or nursing
- Planning to become pregnant

Aranesp<sup>®</sup> has not been studied in pregnant women and its effects on developing babies are not known. It is also not known if Aranesp<sup>®</sup> can pass into human breast milk.

**Talk to your doctor** if you are not sure if you have these conditions or if you have any questions about this information.

Your doctor may monitor your blood pressure and the amount of iron in your blood before you start Aranesp<sup>®</sup> and while you are taking Aranesp<sup>®</sup>. You or your caregiver may also be asked to monitor your blood pressure every day and to report any changes. When the number of red blood cells increases, your blood pressure may also increase, so your doctor may prescribe new or more blood pressure medicine. You may be asked to have certain blood tests, such as hemoglobin, hematocrit or blood iron levels. Also, your doctor may prescribe iron for you to take. Follow your doctor's orders.

## **What are other possible side effects of Aranesp<sup>®</sup>?**

Aranesp<sup>®</sup> may cause serious side effects. See "**What is the most important information I should know about Aranesp<sup>®</sup>?**"

Other side effects of Aranesp<sup>®</sup> include:

- Increased blood pressure; your doctor or caregiver may monitor your blood pressure more frequently.
- Infections
- Cough
- Chest pain
- Antibodies against Aranesp<sup>®</sup> that can block or reduce your body's ability to make red blood cells. If you experience unusual tiredness and lack of energy, **call your doctor**.
- Redness, swelling, pain, or itching at the site of injection. If you notice any signs of redness, swelling, or itching at the site of injection, talk to your doctor.
- Serious allergic reactions. These reactions can cause a rash over the whole body, shortness of breath, wheezing, a drop in blood pressure, swelling around the mouth or eyes, fast pulse, or sweating. If at any time a serious allergic reaction occurs, **stop using Aranesp<sup>®</sup> and call your doctor or emergency medical personnel immediately (for example, call 911)**.

The needle cover on the prefilled syringe contains a derivative of latex. If you know you are allergic to latex, talk to your healthcare provider before using Aranesp<sup>®</sup>.

The most common side effects you may have when taking Aranesp<sup>®</sup> are:

- Increased blood pressure
- Decreased blood pressure
- Body or muscle aches
- Headache
- Diarrhea
- Shortness of breath
- Swelling in your arms or legs
- Fever
- Nausea or vomiting
- Infections
- Chest pain

Some side effects are more common depending on the reasons for which you are taking Aranesp<sup>®</sup>. Talk to your doctor for more information about side effects. Make sure to report any side effects to your doctor.

Aranesp<sup>®</sup> has other side effects that are not listed here. For a complete list, talk to your doctor.

**Call your doctor right away if:**

- You take more than the amount prescribed.
- You are currently taking Aranesp<sup>®</sup> and experience any of these symptoms, which may be a sign of a serious problem:

- Unusual tiredness and lack of energy
- Redness, swelling, pain, or itching at the site of injection and spreading rash over the whole body, shortness of breath, wheezing, a drop in blood pressure, swelling around the mouth or eyes, fast pulse, or sweating
- Convulsion, confusion, dizziness, loss of consciousness
- Increased blood pressure, chest pain, irregular heartbeats
- Stroke, chest pain, shortness of breath, or pain with or without swelling in the legs
- Blood clots in your hemodialysis vascular access port

### **What important information do I need to know about taking Aranesp<sup>®</sup> at home?**

After your doctor has determined that you can safely use Aranesp<sup>®</sup> at home, you or your caregiver will receive instructions on how much Aranesp<sup>®</sup> to use, how to inject it, how often it should be injected, and how to dispose of the unused portions of each vial or prefilled syringe. Your doctor will decide whether to use Aranesp<sup>®</sup> in vials or prefilled syringes. Do not change the way you use Aranesp<sup>®</sup> (including the dose of Aranesp<sup>®</sup>) without consulting your doctor. You should ask your doctor what to do if you miss a dose of Aranesp<sup>®</sup>. **You should always follow your doctor's instructions.**

Be sure to change the site for each injection to avoid soreness at any one site. Occasionally a problem may develop at the injection site. If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your doctor.

If you have a hemodialysis vascular access, continue to check the access to make sure it is working. Call your doctor or dialysis center right away if you have any problems or questions.

### **How should I store Aranesp<sup>®</sup>?**

Aranesp<sup>®</sup> should be kept in its original carton to protect it from light, and stored in the refrigerator at 2° to 8°C (36° to 46°F). Do not place Aranesp<sup>®</sup> in the freezer. Do not use a vial or prefilled syringe of Aranesp<sup>®</sup> that has been frozen, left in light, or improperly refrigerated. It is important that Aranesp<sup>®</sup> be stored and used as stated in these instructions. Contact your healthcare provider with any questions about storage.

When traveling, transport Aranesp<sup>®</sup> in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the Aranesp<sup>®</sup> vial or prefilled syringe does not touch the coolant. Once you arrive, your Aranesp<sup>®</sup> should be placed in a refrigerator as soon as possible.

### **How do I take Aranesp<sup>®</sup>?**

When you receive your Aranesp<sup>®</sup>, always check to see that:

- The name Aranesp<sup>®</sup> appears on the package and vial or prefilled syringe label.
- The expiration date on the vial or prefilled syringe label has not passed. **You should not use a vial or prefilled syringe after the date on the label.**

- The strength of the Aranesp<sup>®</sup> vial or prefilled syringe (number of micrograms [mcg] in the colored square on the package and on the vial or prefilled syringe label) is the same as the doctor prescribed.
- The Aranesp<sup>®</sup> liquid in the vial or prefilled syringe is clear and colorless. Do not use Aranesp<sup>®</sup> if the liquid in the vial or prefilled syringe appears discolored or cloudy or if the liquid appears to contain lumps, flakes, or particles.
- The Aranesp<sup>®</sup> vial has a color cap on the top of the vial. Do not use a vial of Aranesp<sup>®</sup> if the color cap on the top of the vial has been removed or is missing.
- Do not use Aranesp<sup>®</sup> in a prefilled syringe if the grey cover on the needle is off, or the needle guard (yellow sleeve on the syringe) has been activated (pulled to extend over the needle). If you are using a vial of Aranesp<sup>®</sup>, only use the type of disposable syringe that your doctor prescribes.

The doctor or nurse will give you instructions on how to measure your dose of Aranesp<sup>®</sup>. This dose will be measured in milliliters. You should only use a syringe that is marked in tenths of milliliters, or mL (for example, 0.2 mL). The doctor or nurse may refer to an “mL” as a “cc” (1 mL = 1 cc). Using an unmarked syringe can lead to a mistake in the dose. If you do not use the correct syringe, you could inject too much or too little Aranesp<sup>®</sup>.

**Only use disposable syringes and needles. Use the syringes and needles only once and dispose of them as instructed by your healthcare provider.**

**IMPORTANT: TO HELP AVOID POSSIBLE INFECTION, FOLLOW THESE INSTRUCTIONS.**

### **Setting up for an injection**

1. Find a clean, flat work surface such as a table.
2. If you are using a vial, remove a vial of Aranesp<sup>®</sup> from the refrigerator. If you are using a prefilled syringe, tear off one syringe (in wrapper) from the strip and place the others back in the refrigerator. Keep the syringe in its wrapper until you are ready to prepare your dose. Do not freeze Aranesp<sup>®</sup> or use a vial or prefilled syringe that has been frozen. Do not shake Aranesp<sup>®</sup> or leave vials or syringes exposed to bright light. Vigorous shaking or exposure to light may denature Aranesp<sup>®</sup> causing it to become biologically inactive.
3. Remove the vial or prefilled syringe of Aranesp<sup>®</sup> from its carton and place it on your flat work surface. Allow it to reach room temperature. This should take about 30 minutes. During this time, cover the vial or prefilled syringe to protect the solution from light.
4. You should use a vial or prefilled syringe only once. Do not put the needle through the rubber stopper more than once. **DO NOT SHAKE THE VIAL OR PREFILLED SYRINGE.** Shaking may damage Aranesp<sup>®</sup>. If the Aranesp<sup>®</sup> vial or prefilled syringe has been shaken vigorously, the solution may appear foamy and it should not be used.

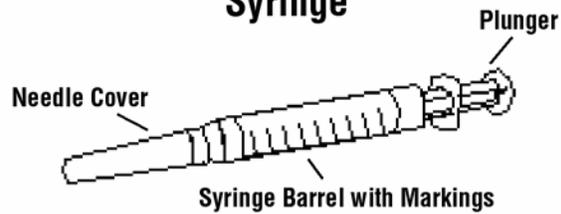
5. Assemble the supplies you will need for an injection:

- Aranesp<sup>®</sup> vial and the correct disposable syringe and needle

### Vial



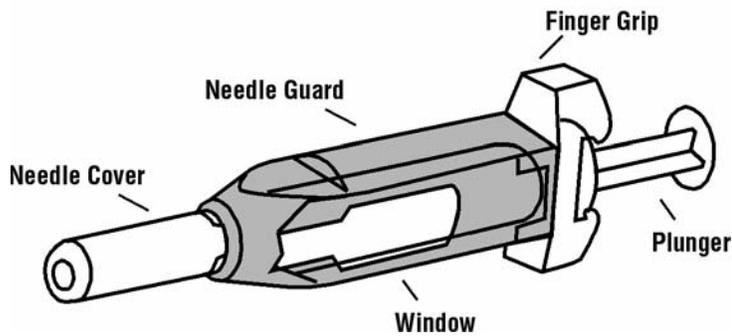
### Disposable Syringe



OR

- Aranesp<sup>®</sup> prefilled syringe with a transparent (clear) yellow plastic needle guard attached

### Prefilled Syringe



- Two alcohol swabs and one cotton ball or gauze. Open one alcohol wipe if you are using a prefilled syringe. Open two alcohol wipes if you are using a vial and disposable syringe.

### Alcohol Swab



### Cotton Ball



- Puncture-proof disposal container

6. Wash your hands with soap and warm water.

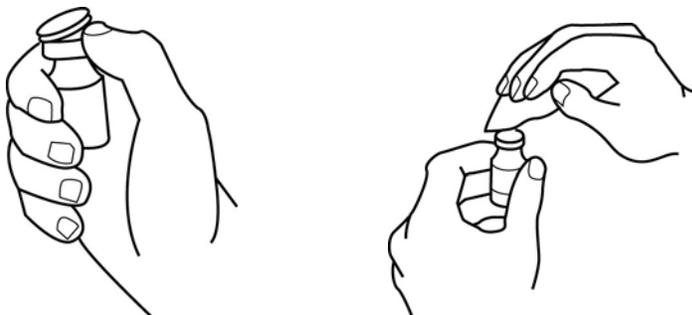


### **How to prepare the dose of Aranesp<sup>®</sup>**

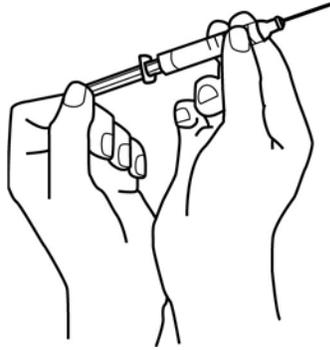
***If you are using Aranesp<sup>®</sup> in a vial, follow the instructions in Section A. If you are using Aranesp<sup>®</sup> in a prefilled syringe, follow the instructions in Section B.***

#### **Section A. Preparing the dose of Aranesp<sup>®</sup> using a vial and disposable syringe**

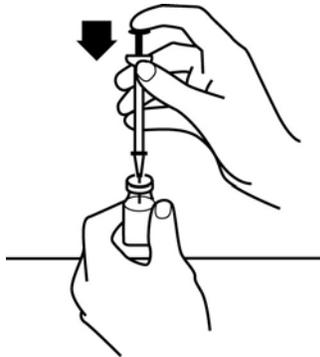
1. Take the color cap off the vial. Clean the rubber stopper with one alcohol swab.



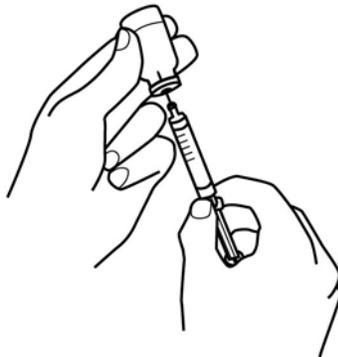
2. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. You should dispose of that syringe in the puncture-proof disposal container. If the syringe package is undamaged, open the package and remove the syringe.
3. Pull the needle cover straight off the syringe. Then, pull back on the plunger to draw air into the syringe. The amount of air drawn into the syringe should be the same amount (mL or cc) as the dose of Aranesp<sup>®</sup> that your doctor prescribed.



4. Keep the vial on your flat work surface and insert the needle straight down through the rubber stopper.
5. Push the plunger of the syringe down to inject the air from the syringe into the vial of Aranesp<sup>®</sup>.



6. Keeping the needle inside the vial, turn the vial upside down. Make sure that the tip of the needle is in the Aranesp<sup>®</sup> liquid.



7. Keeping the vial upside down, slowly pull back on the plunger to fill the syringe with Aranesp<sup>®</sup> liquid to the number (mL or cc) that matches the dose your doctor prescribed.
8. Keeping the needle in the vial, check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Then slowly push the plunger up to force the air bubbles out of the syringe. Keep the tip of the needle in the liquid and once again pull the plunger back to the number on the syringe that matches your dose. Check again for air bubbles.

The air in the syringe will not hurt you, but too large an air bubble can reduce your dose of Aranesp<sup>®</sup>. If there are still air bubbles, repeat the steps above to remove them.

9. Check again to make sure that you have the correct dose in the syringe. It is important that you use the exact dose prescribed by your doctor.
10. Lay the vial on its side with the needle still in it until after you have selected and prepared a site for injection. This will keep the needle from touching anything before you use it.

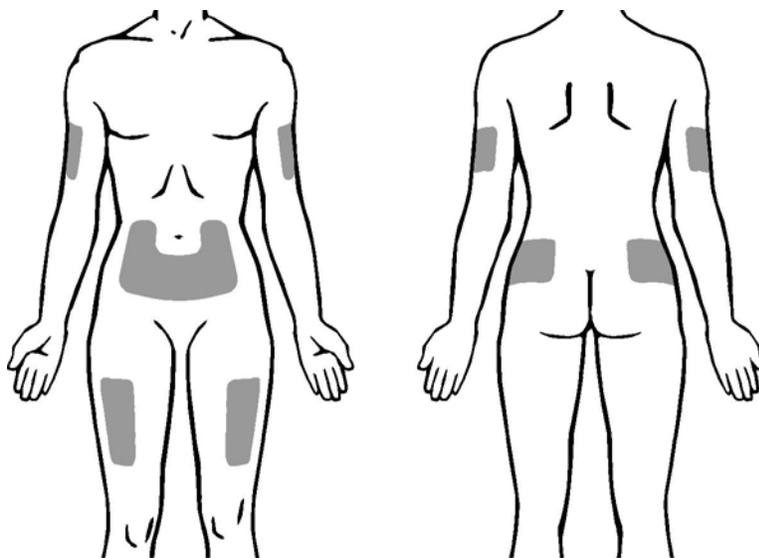
***Go directly to the section “Selecting and preparing the injection site.”***

### **Section B. Preparing the dose of Aranesp<sup>®</sup> using a prefilled syringe**

1. 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. Dispose of that syringe in the puncture-proof disposal 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.
2. Hold the syringe with the needle pointing up to prevent the Aranesp<sup>®</sup> from leaking out of the needle. Carefully pull the needle cover straight off.
3. Still holding the syringe up, slowly push the plunger to the line on the syringe that matches the dose your doctor has prescribed.
4. 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.
5. Check again to make sure that you have the correct dose in the syringe. It is important that you use the exact dose prescribed by your doctor.
6. When you put the syringe down on your working surface, be careful not to allow the needle to touch anything.

### **Selecting and preparing the injection site**

1. Choose an injection site. Four recommended injection sites for Aranesp<sup>®</sup> include:
  - The outer area of the upper arms
  - The abdomen (except for the two-inch area around the navel)
  - The front of the middle thighs
  - The upper outer areas of the buttocks

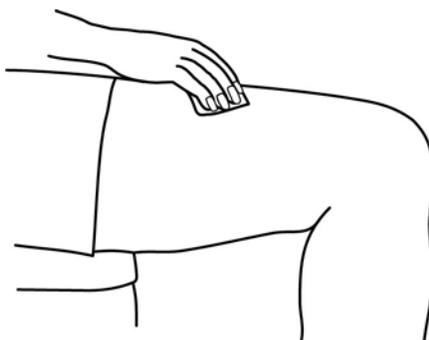


**Front**

**Back**

Choose a new site each time you inject Aranesp<sup>®</sup>. Choosing a new site can help avoid soreness at any one site. Do not inject Aranesp<sup>®</sup> into an area that is tender, red, bruised, hard, or that has scars or stretch marks.

2. Clean the injection site with a new alcohol swab.

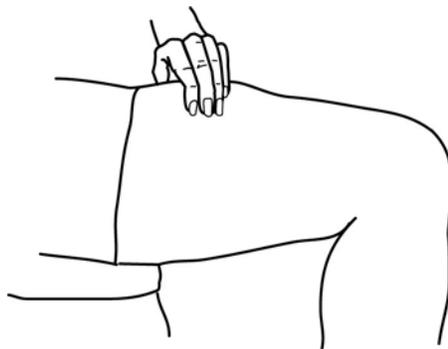


## Injecting the dose of Aranesp<sup>®</sup> from a vial or prefilled syringe

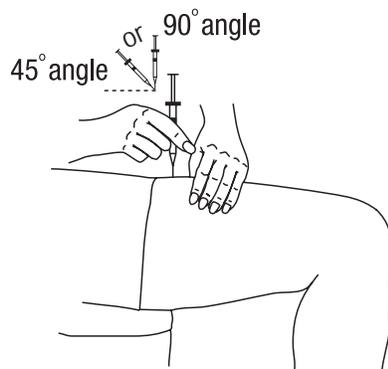
For patients not on hemodialysis:

1. Hold the syringe in the hand that you will use to inject Aranesp<sup>®</sup>. Use the other hand to pinch a fold of skin at the cleaned injection site.

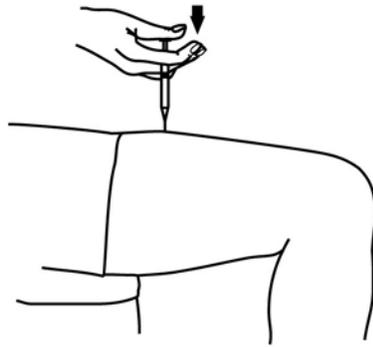
Note: If using a prefilled syringe with a needle guard, hold the syringe barrel through the two needle guard windows when giving the injection.



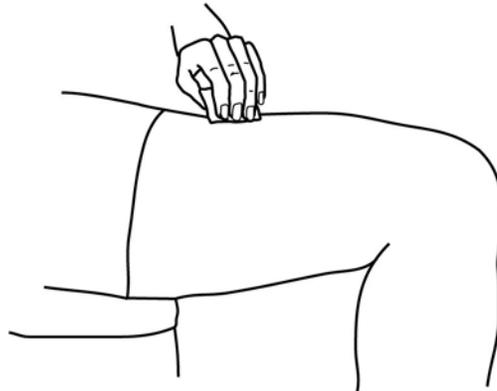
2. Holding the syringe like a pencil, use a quick “dart like” motion to insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degrees) into the skin.



3. After the needle is inserted, let go of the skin. Pull the plunger back slightly. If no blood appears, slowly push the plunger all the way down, until all the Aranesp<sup>®</sup> is injected. If blood comes into the syringe, do not inject Aranesp<sup>®</sup> because the needle has entered a blood vessel. Withdraw the syringe and discard it in the puncture-proof disposal container. Repeat the steps to choose and clean a new injection site and prepare a new syringe. Remember to check again for blood before injecting Aranesp<sup>®</sup>.



4. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.



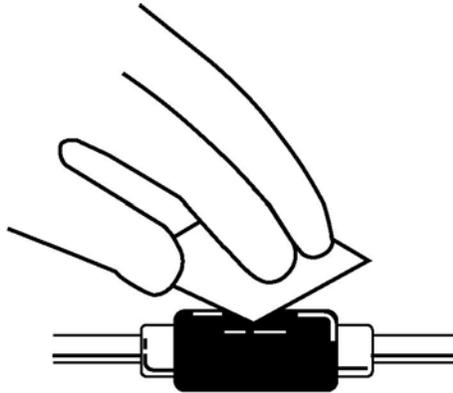
5. You should ONLY use a disposable syringe and Aranesp<sup>®</sup> vial or prefilled syringe once. You should discard the disposable syringe and vial or prefilled syringe with any remaining Aranesp<sup>®</sup>.

***If a prefilled syringe was used, go directly to the section “Activation of the needle guard on used prefilled syringes.”***

***If a disposable syringe was used with a vial of Aranesp<sup>®</sup>, go directly to the section “Disposal of syringes and needles.”***

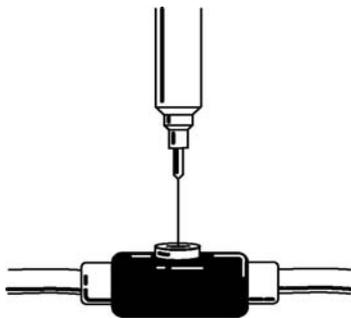
**For patients on hemodialysis:**

1. Clean the venous port of the hemodialysis tubing with a new alcohol swab.

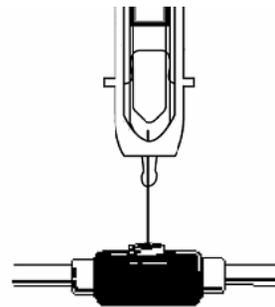


2. Insert the needle of the syringe into the cleaned venous port and push the plunger all the way down to inject all the Aranesp<sup>®</sup>.

Using  
disposable syringe



Using prefilled syringe  
with needle guard



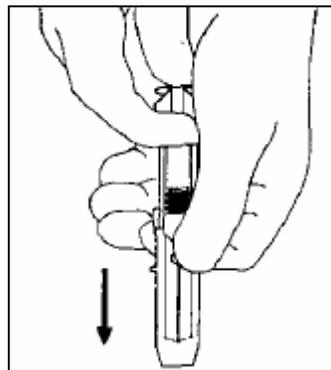
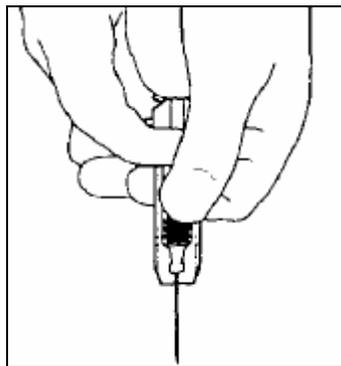
Remove the syringe from the venous port.

***If a disposable syringe was used with a vial of Aranesp<sup>®</sup>, go directly to the section “Disposal of syringes and needles.”***

### Activation of the needle guard on used prefilled syringes

1. After injecting Aranesp<sup>®</sup> 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, sliding it completely over the needle until the needle guard clicks into place.

**NOTE: If an audible click is not heard, the needle guard may not be completely activated.**



### Disposal of syringes and needles

Dispose of the syringe and needle or the syringe with activated needle guard as instructed by your healthcare provider, or by following these steps:

- Do not throw the needle or syringe in the household trash or recycle.
- DO NOT put the needle cover back on the needle. Place the used needle, needle cover, 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.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- **Always** keep the container out of the reach of children.
- 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.**

### **General Information about Aranesp<sup>®</sup>**

Doctors can prescribe medicines for conditions that are not in this leaflet. Use Aranesp<sup>®</sup> only for what your doctor prescribed. Do not give it to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet gives the most important information about Aranesp<sup>®</sup>. For more information, talk with your doctor or healthcare provider. You can also access more information at the following website: [www.aranesp.com](http://www.aranesp.com).

Active ingredient: darbepoetin alfa

Inactive ingredients: polysorbate solution or albumin solution

**AMGEN<sup>®</sup>**

**Manufactured by:**

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.  
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