

Aranesp®

(Air-uh-nesp)

(darbepoetin alfa)

Single-use Prefilled SureClick™ Autoinjector

Information for Patients

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

What important information should I know about Aranesp®?

Aranesp® works by stimulating your bone marrow to make more red blood cells. You will be asked to have blood tests that will measure the number of red blood cells to see if Aranesp® is working. Your doctor may refer to the results of your blood tests as hemoglobin and/or hematocrit. It is important to keep all appointments for blood tests to allow your doctor to adjust the dosage of Aranesp® as needed.

If your hemoglobin is kept too high (over 12 g/dL):

- You increase the chance of heart attack, stroke, heart failure, blood clots and death
- Your tumor may grow faster (if you are a patient with cancer)

If you are a patient with cancer who has completed all of your planned chemotherapy treatment, Aranesp® treatment may increase your chance of death regardless of hemoglobin level.

If you undergo surgery while taking an erythropoietin product, your physician may prescribe a blood thinner to prevent blood clots.

You should talk with your doctor if you have any questions or concerns about this **important safety information**.

Please also read **“What are the possible or reasonably likely side effects of Aranesp®?”** below.

What is Aranesp®?

Aranesp® (Air-uh-nesp) is a man-made form of the protein human erythropoietin (ee-rith-row-po-eh-tin). Aranesp® 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 and if so, you may be able to avoid the need for red blood cell transfusion. Your doctor will prescribe the lowest dose of Aranesp® needed to avoid red blood cell transfusions because of the concerns discussed in **“What important information should I know about Aranesp®?”** above.

Aranesp[®] is used to treat anemia (a lower than normal number of red blood cells).

Aranesp[®] may be used to treat your anemia if it is caused by:

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

While you are being treated with Aranesp[®], you will be having blood tests (called hemoglobin and/or hematocrit) to check the number of red blood cells your body is producing. The amount of time it takes to reach the red blood cell level that is right for you, and the dose of Aranesp[®] needed to make the red blood cell level rise, is different for each person. You may need Aranesp[®] dose adjustments before you reach your correct dose of Aranesp[®] and the correct dose may change over time.

Who should not take Aranesp[®]?

You should not take Aranesp[®] if you have:

- High blood pressure that is not controlled (uncontrolled hypertension).
- Allergies to Aranesp[®] or other erythropoietins.
- Previous allergic reactions to any of the ingredients in Aranesp[®]. See the list of ingredients in Aranesp[®] at the end of the leaflet.

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[®]?

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, clotting disorders)

In addition, you should tell your doctor if you are:

- Pregnant or nursing
- Planning to become pregnant

Aranesp[®] has not been studied in pregnant women and its effects on developing babies are not known. It is also not known if Aranesp[®] can get 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[®] and while you are taking Aranesp[®]. 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. Be sure to follow your doctor's orders.

What are the possible or reasonably likely side effects of Aranesp®?

Your blood pressure may increase when the number of red blood cells rises, so your doctor or caregiver may monitor your blood pressure more frequently. Some people have also had infections, low blood pressure, fevers, headaches, muscle aches or soreness, nausea, diarrhea, leg swelling, cough, or chest pain. If you experience any of these symptoms, you should call your doctor.

If you are on hemodialysis, there is a risk of blood clots forming at your vascular access. Call your doctor or dialysis center if you think your access is blocked.

Some patients may have an increased risk of blood clots forming in blood vessels, especially in the leg veins (venous thrombosis). In some patients, pieces of blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus). **Call your doctor if you experience chest pain, shortness of breath, or pain in the legs with or without swelling.**

It is possible that your body may make antibodies against Aranesp®. Antibodies to Aranesp® 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.**

Some people experience redness, swelling, pain or itching at the site of injection. This reaction may be an allergy to the ingredients in Aranesp®, or it may be a local irritation. If you notice any signs of redness, swelling, or itching at the site of injection, talk to your doctor.

Serious allergic reactions can also happen. 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® 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®.

The most common side effects you may have when taking Aranesp® 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[®]. Talk to your doctor for more information about side effects. Make sure to report any side effects to your doctor.

Aranesp[®] 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[®] 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 to 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 and/or swelling in the legs
 - Blood clots in your hemodialysis vascular access port

What important information do I need to know about taking Aranesp[®] at home?

In some rare cases, your doctor may decide that you will be able to use Aranesp[®] at home. If your doctor has determined that you can safely use Aranesp[®] at home, you and/or your caregiver will receive instructions on how much Aranesp[®] to use, how to inject it, how often it should be injected, and how to dispose of the used vial, prefilled syringe or autoinjector. Your doctor will decide whether to use Aranesp[®] in vials, prefilled syringes, or prefilled autoinjectors. Do not change the way you use Aranesp[®] (including the dose of Aranesp[®]) without consulting your doctor. You should ask your doctor what to do if you miss a dose of Aranesp[®]. **You should always follow your doctor's instructions.**

How should I store Aranesp[®]?

- Always keep the single-use prefilled SureClick[™] autoinjector in the original box to protect Aranesp[®] from light. Do not leave the autoinjector exposed to light longer than necessary to inject Aranesp[®].
- Keep Aranesp[®] inside the refrigerator at 2° to 8°C (36° to 46°F). **DO NOT FREEZE.**
- When traveling, transport Aranesp[®] in its original box in an insulated container with an ice pack. To avoid freezing, make sure the Aranesp[®] prefilled SureClick[™] autoinjector does not touch the ice pack. Once you arrive, your Aranesp[®] should be placed in a refrigerator as soon as possible.

Do not use a prefilled SureClick™ autoinjector that has been frozen, improperly left in light, or improperly refrigerated. It is important that Aranesp® be stored and used as stated in these instructions. Contact your pharmacist or healthcare provider with any questions about storage.

How do I take Aranesp®?

This section contains information on how to give yourself an injection of Aranesp® using the single-use, prefilled SureClick™ autoinjector. You will need to give yourself the injection into the tissue just under the skin. This is called a subcutaneous injection. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. **If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.**

To give yourself a subcutaneous injection you will need:

- A new single-use Aranesp® prefilled SureClick™ autoinjector
- Alcohol or sterile wipe
- A puncture-proof container so you can dispose of the used autoinjector safely

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

How do I prepare for an injection of Aranesp®?

1. Take your autoinjector out of the refrigerator. Keep the autoinjector in its box until you are ready to use it.
 - **Do not shake the autoinjector or leave exposed to bright light.** Vigorous shaking or exposure to light could cause the drug to become inactive. If the Aranesp® prefilled SureClick™ autoinjector has been shaken vigorously, the solution may appear foamy and it should not be used.
 - **Do not use an autoinjector that has been frozen, improperly left in light, or improperly refrigerated.**
2. Check that it is the correct dose that your doctor has prescribed.
3. Check the expiration date on the autoinjector label. **If the last day of the month shown has passed, do not use the autoinjector** and contact your pharmacist or healthcare provider for assistance.
4. Remove the autoinjector from the box. For a more comfortable injection, leave the autoinjector at room temperature for about 30 minutes. During this time, cover the autoinjector to protect the solution from light.
 - **Do not** warm Aranesp® in any other way (for example, do not warm it in a microwave or in hot water). **Do not** leave the autoinjector exposed to direct sunlight.
 - **Do not** remove the grey needle shield from the autoinjector until you are ready to inject.
 - **NEVER** put the grey needle shield back into the autoinjector.