

FDA Approved: 11-19-08

MEDICATION GUIDE

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

Read this Medication Guide before you start Aranesp, each time you refill your prescription, and if you are told by your healthcare provider that there is new information about Aranesp. This Medication Guide was revised August 2008. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment. Talk with your healthcare provider regularly about the use of Aranesp and ask if there is new information about Aranesp.

What is the most important information I should know about Aranesp?

Using Aranesp can lead to death or other serious side effects.

Patients with cancer:

Your tumor may grow faster and you may die sooner when Aranesp is used experimentally to try to raise your hemoglobin beyond the amount needed to avoid red blood cell transfusion or given to patients who are not getting strong doses of chemotherapy. It is not known whether these risks exist when Aranesp is given according to the FDA-approved directions for use.

You should discuss with your doctor:

- Why Aranesp treatment is being prescribed.
- What are the chances you will get red blood cell transfusions if you do not take Aranesp.
- What are the chances you will get red blood cell transfusions even if you take Aranesp.
- How taking Aranesp may affect the success of your cancer treatment.

If you decide to take Aranesp, your healthcare provider should prescribe the smallest dose of Aranesp to lower the chance of getting red blood cell transfusions.

- After you have finished your chemotherapy course, Aranesp treatment should be stopped.
- Aranesp does not improve the symptoms of anemia (lower than normal number of red blood cells), quality of life, fatigue, or well-being for patients with cancer.

All patients, including patients with cancer or chronic kidney failure:

- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with Aranesp to a hemoglobin level above 12 g/dL.
- You may get blood clots at any time while taking Aranesp. If you are receiving Aranesp and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus).

Call your healthcare provider or get medical help right away if you have any of these symptoms of blood clots:

- Chest pain

- Trouble breathing or shortness of breath
- Pain in your legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion, trouble speaking, or trouble understanding others' speech
- Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body
- Sudden trouble seeing
- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working. If you are a patient with chronic kidney failure and have a hemodialysis vascular access, blood clots may form in this access.

Also see **“What are the possible side effects of Aranesp?”** below.

What is Aranesp?

Aranesp is a man-made form of the protein human erythropoietin that is given to patients to lessen the need for red blood cell transfusions. Aranesp stimulates your bone marrow to make more red blood cells. Having more red blood cells raises your hemoglobin level. If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen even if you take Aranesp and do not have an increase in your hemoglobin level.

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

- Chronic kidney failure (you may or may not be on dialysis)
- Chemotherapy that is used to treat some types of cancer

Who should not take Aranesp?

Do not take Aranesp if you:

- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have allergies to any of the ingredients in Aranesp. See the end of this Medication Guide for a complete list of ingredients in Aranesp.

What should I tell my healthcare provider before taking Aranesp?

Aranesp may not be right for you. **Tell your healthcare provider about all your health conditions**, including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Are pregnant or planning to become pregnant. It is not known if Aranesp will harm your unborn baby.
- Are breast-feeding or planning to breast-feed. It is not known if Aranesp passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

How should I take Aranesp?

- Continue to follow your healthcare provider’s instructions for diet, dialysis, and medicines, including medicines for high blood pressure, while taking Aranesp.
- Have your blood pressure checked as instructed by your healthcare provider.
- If you or your caregiver has been trained to give Aranesp shots (injections) at home:
 - Be sure that you read, understand, and follow the “Patient Instructions for Use” that come with Aranesp.
 - Take Aranesp exactly as your healthcare provider tells you to. Do not change the dose of Aranesp unless told to do so by your healthcare provider.
 - Your healthcare provider will show you how much Aranesp to use, how to inject it, how often it should be injected, and how to safely throw away the used vial, syringes, and needles.
 - If you miss a dose of Aranesp, call your healthcare provider right away and ask what to do.
 - If you take more than the prescribed amount of Aranesp, call your healthcare provider right away.

What are the possible side effects of Aranesp?

Aranesp may cause serious side effects. See “**What is the most important information I should know about Aranesp?**”

Other side effects of Aranesp, which may also be serious, include:

- **High blood pressure in patients with chronic kidney failure.** Your blood pressure may go up or be difficult to control with blood pressure medicine while taking Aranesp. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine.
- **Seizures.** If you have any seizures while taking Aranesp, get medical help right away and tell your healthcare provider.
- **Antibodies to Aranesp.** Your body may make antibodies to Aranesp. These antibodies can block or lessen your body’s ability to make red blood cells and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking Aranesp.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using Aranesp and call your healthcare provider or get medical help right away.

The needle cover on the prefilled syringe contains a material that is like latex. If you know you are allergic to latex, talk to your healthcare provider before using Aranesp.

Common side effects of Aranesp include:

- Swelling in cancer patients
- Rash
- Injection site pain

These are not all of the possible side effects of Aranesp. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Aranesp?

- Do not shake Aranesp.

- Protect Aranesp from light.
- Store Aranesp in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze.** Do not use Aranesp that has been frozen.

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

General information about Aranesp

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use Aranesp only for the condition for which it has been prescribed. Do not give Aranesp to other people even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Aranesp. If you would like more information about Aranesp, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Aranesp that is written for healthcare professionals. For more information, go to the following website: www.aranesp.com or call 1-800-77-AMGEN.

What are the ingredients in Aranesp?

Active Ingredient: darbepoetin alfa

Inactive Ingredients:

- polysorbate solution: polysorbate 80, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, and sodium chloride in Water for injection, USP.
- albumin solution: albumin (human), sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, and sodium chloride in Water for Injection, USP.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.



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