

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

Read this Medication Guide:

- before you start Aranesp.
- if you are told by your healthcare provider that there is new information about Aranesp.
- if you are told by your healthcare provider that you may inject Aranesp at home, read this Medication Guide each time you receive a new supply of medicine.

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?

Aranesp may cause serious side effects that can lead to death, including:

For people with cancer:

- Your tumor may grow faster and you may die sooner if you choose to take Aranesp. Your healthcare provider will talk with you about these risks.

For all people who take Aranesp, including people with cancer or chronic kidney disease:

- **Serious heart problems, such as heart attack or heart failure, and stroke.** You may die sooner if you are treated with Aranesp to increase red blood cells (RBCs) to near the same level found in healthy people.
- **Blood clots.** Blood clots may happen at any time while taking Aranesp. If you are receiving Aranesp for any reason 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. Blood 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:
 - 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

See "**What are the possible side effects of Aranesp?**" below for more information.

If you decide to take Aranesp, your healthcare provider should prescribe the smallest dose of Aranesp that is necessary to reduce your chance of needing red blood cell transfusions.

What is Aranesp?

Aranesp is a prescription medicine used to treat anemia. People with anemia have a lower-than-normal number of RBCs. Aranesp works like the human protein called erythropoietin to help your body make more RBCs. Aranesp is used to reduce or avoid the need for RBC transfusions.

Aranesp may be used to treat anemia if it is caused by:

- Chronic kidney disease (you may or may not be on dialysis).
- Chemotherapy that will be used for at least two months after starting Aranesp.

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 if you take Aranesp, even if you do not have an increase in your hemoglobin level.

Aranesp has not been proven to improve the quality of life, fatigue, or well-being.

Aranesp **should not be used** for the treatment of anemia:

- If you have cancer and you will not be receiving chemotherapy that may cause anemia.
- If you have a cancer that has a high chance of being cured. Talk with your healthcare provider about the kind of cancer you have.
- If your anemia caused by chemotherapy treatment can be managed by RBC transfusion.
- In place of emergency treatment for anemia (RBC transfusions).

It is not known if Aranesp is safe and effective in children who have cancer.

Who should not take Aranesp?

Do not take Aranesp if you:

- Have cancer and have not been counseled by your healthcare provider about treatment with Aranesp.
- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with Aranesp or other erythropoietin protein medicines.
- Have had a serious allergic reaction to Aranesp.

Before taking Aranesp, tell your healthcare provider about all of your medical conditions, including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Are allergic to latex. The needle cover on the prefilled syringe contains latex.
- Receive dialysis treatment.
- Are pregnant or plan to become pregnant. It is not known if Aranesp may harm your unborn baby. Talk to your healthcare provider about possible pregnancy and birth control choices that are right for you.
- Are breastfeeding or plan to breastfeed. It is not known if Aranesp passes into breast milk.

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

How should I take Aranesp?

- If you or your caregiver has been trained to give Aranesp shots (injections) at home:
 - Be sure that you read, understand, and follow the “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 vials, 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 dose of Aranesp, call your healthcare provider right away.
- During treatment with Aranesp, continue to follow your healthcare provider’s instructions for diet and medicines.
- Have your blood pressure checked as instructed by your healthcare provider.

What are the possible side effects of Aranesp?

Aranesp may cause serious side effects, including:

- See “**What is the most important information I should know about Aranesp?**”
- **High blood pressure.** High blood pressure is a common side effect of Aranesp in people with chronic kidney disease. 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 RBCs 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 skin rash, itching, 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.
- **Severe skin reactions.** Signs and symptoms of severe skin reactions with Aranesp may include: skin rash with itching, blisters, skin sores, peeling or areas of skin coming off. If you have any signs or symptoms of a severe skin reaction, stop using Aranesp and call your healthcare provider or get medical help right away.

Common side effects of ARANESP include:

- shortness of breath
- cough
- low blood pressure during dialysis
- abdominal pain
- edema (swelling) of the arms or legs

These are not all 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.
- Store Aranesp in the carton it comes in to protect it from light.
- Store Aranesp in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze Aranesp.** Do not use Aranesp that has been frozen.
- Throw away the Aranesp vial or prefilled syringe after one use. Do not re-use even if there is medicine left.

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. Do not use Aranesp for a condition for which it was not prescribed. Do not give Aranesp to other people even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about Aranesp that is written for healthcare professionals.

What are the ingredients in Aranesp?

Active ingredient: darbepoetin alfa

Inactive ingredients: polysorbate 80, sodium chloride, sodium phosphate dibasic anhydrous, and sodium phosphate monobasic monohydrate in Water for Injection, USP.

The logo for Amgen, featuring the word "AMGEN" in a bold, black, sans-serif font with a registered trademark symbol (®) to the upper right.

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For more information, go to the following website: www.aranesp.com or call 1-800-77-AMGEN.

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

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