

A treatment to fit your needs

Aranesp® (darbepoetin alfa) is a prescription medicine used to treat a lower than normal number of red blood cells (anemia) caused by chronic kidney disease in patients on dialysis and not on dialysis.



Aranesp[®] should not be used for the treatment of anemia in place of emergency treatment for anemia (red blood cell transfusions).

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

Using Aranesp[®] can lead to death or other serious side effects. If you decide to take Aranesp[®], your healthcare provider should prescribe the smallest dose that is necessary to reduce your chance of needing red blood cell transfusions.



NEXT

About anemia

Anemia is a condition in which the body has fewer red blood cells than normal.

Your red blood cells have the important job of carrying oxygen around the body. The fewer you have, the harder your body has to work to do simple tasks, such as making your heart beat and your muscles move.



Normal number of red blood cells



Fewer red blood cells





Please read the Important Safety Information for Aranesp® on pages 12–15.

How does chronic kidney disease cause anemia?

If your doctor has diagnosed you with anemia due to chronic kidney disease, it means your kidneys are not making enough erythropoietin (ee-rith-row-PO-eh-tin).

Erythropoietin is the hormone that tells your body to create new red blood cells.



Know your treatment options

Iron supplements

Many patients with chronic kidney disease do not have enough iron. The body needs iron to make red blood cells and carry oxygen.

Erythropoiesis-stimulating agents (ESAs)

ESAs act like erythropoietin, which tells your body to make more red blood cells. Having enough iron is important to ESA therapy. An ESA, like Aranesp[®], is available only through your doctor, who will review the risks and benefits of this specific treatment.

Red blood cell transfusions

Transfusion can quickly increase the number of red blood cells within 1 to 4 hours. Your doctor will cover the benefits and risks of transfusion, including the possible reactions and infections that could result.

BACK

NEXT



Your doctor will help you choose the best treatment for your anemia.



5

BACK NEXT

About Aranesp[®]

Aranesp[®] is a medicine that acts like a hormone in the body called erythropoietin. Aranesp[®] helps the body create more red blood cells.

More red blood cells increase your hemoglobin (Hb) level, helping give your tissues and organs the oxygen they need to function properly.

It is important for your doctor to monitor your Hb levels regularly to ensure Aranesp[®] is working right for you. Regular monitoring helps your doctor to make sure that your Hb is not going up too high or too quickly.



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BACK

NEXT

Please read the Important Safety Information for Aranesp[®] on pages 12–15.

Aranesp[®] has been prescribed since 2001 to patients with chronic kidney disease on dialysis and patients not on dialysis.



Please read the Important Safety Information for Aranesp® on pages 12–15.

Is Aranesp[®] right for you?

Aranesp[®] is not right for everyone. Tell your nurse and doctor about any conditions you have, especially if you:

- Have high blood pressure
- Have heart disease
- · Have had a seizure (convulsion) or stroke
- Are pregnant or planning to become pregnant
- Are breast-feeding or planning to breast-feed
- · Have any allergies, including to latex
- Have cancer
- · Have any other medical conditions

These conditions can have a serious impact on the way your body responds to Aranesp[®]. Your doctor needs to be aware of these conditions in order to decide if Aranesp[®] is right for you.

BACK

NEXT



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Tell your doctor about all of the medications you take, including vitamins, prescription and nonprescription medications, and herbal supplements. They can affect your anemia or interact with Aranesp[®], so it's very important information for your doctor to know. Your doctor may have you start to take or change to a different blood pressure medication. It is very important to have well-controlled blood pressure levels while you are being treated with Aranesp[®].

If you know you are allergic to latex, talk to your healthcare provider before using Aranesp[®] because the needle cover on the prefilled syringe contains latex.



How to take Aranesp[®]

If you are on dialysis:

- Your doctor will decide if you will take Aranesp[®] in your dialysis facility or if you and/or your caregiver will be trained to self-inject Aranesp[®] at home.
- You can be treated once a week or once every 2 weeks.
- If you are on hemodialysis, you should receive Aranesp® during dialysis treatment.

If you are not on dialysis:

• You are usually treated once every 4 weeks.

Aranesp® should not be used in place of red blood cell transfusion for the immediate correction of anemia.

BACK

NEXT



Your doctor will determine the right hemoglobin level for you and treat you with the smallest dose of Aranesp[®] needed to reduce your need for blood transfusion.



BACK



Indications

Aranesp[®] is a prescription medicine used to treat a lower than normal number of red blood cells (anemia) caused by chronic kidney disease in patients on dialysis and not on dialysis.

Aranesp[®] is a prescription medicine used to treat a lower than normal number of red blood cells (anemia) caused by chemotherapy that will be used for at least two months after starting Aranesp[®].

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 for at least 2 more months
- If you have a cancer that has a high chance of being cured
- In place of emergency treatment for anemia (red blood cell transfusions)

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

Important Safety Information

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

For people with cancer:

- In patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers: Your tumor may grow faster and you may die sooner if you choose to take Aranesp[®].
- Your healthcare provider has received special training in order to prescribe Aranesp[®] and will talk with you in detail 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 are going to have surgery, talk with your healthcare provider about whether you need to take a blood thinner to lessen the chance of blood clots during or following surgery.
- 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 or swelling in your legs
 - 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 decide to take Aranesp[®], your healthcare provider should prescribe the smallest dose that is necessary to reduce your chance of needing RBC transfusions.





If your hemoglobin level stays too high or 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.

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 medicines.
- Have had a serious allergic reaction to Aranesp®.

Before taking Aranesp[®], tell your doctor if you: have heart disease; have high blood pressure; have had a seizure or stroke; or if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed.

If you know you are allergic to latex, talk to your healthcare provider before using Aranesp[®] because the needle cover on the prefilled syringe contains latex.

Aranesp[®] may cause other serious side effects:

High blood pressure. High blood pressure is a common side effect of Aranesp[®] in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medication 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.



- Seizures. If you have seizures while taking Aranesp[®], get medical help right away and tell your healthcare provider.
- Antibodies to Aranesp[®]. Your body may make antibodies to Aranesp[®] that 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 rash over your whole body, shortness of breath, wheezing, dizziness and fainting due to 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.

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[®]. Tell your healthcare provider about any side effects that bother you or do not go away.

You are encouraged to report negative side effects of prescription drugs to the US Food and Drug Administration (FDA). Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.







Use this page for notes or things you might want to ask



BACK

NEXT

16 Please read the Important Safety Information for Aranesp[®] on pages 12–15.

Keep track of your hemoglobin (Hb)

Use this page to note your Hb test results

date:	level:	date:	level:
date:	level:	date:	level:
date:	level:	date:	level:
date:	level:	date:	level:
date:	level:	date:	level:
date:	level:	date:	level:
date:	level:	date:	level:

Your doctor will determine the appropriate Hb level for you to reduce your need for blood transfusions.



17 Please read the Important Safety Information for Aranesp® on pages 12–15.

What you can do

You know your doctor is in charge of treating your anemia. But there are also many things you can do to help manage your anemia, such as:

- · Learn more about chronic kidney disease, anemia, and dialysis
- Talk with your healthcare team and other patients with anemia
- Keep all of your dialysis appointments and stay for your full treatment
- Keep track of your lab test results, particularly your hemoglobin
- Use your Lab Tracker, which you can download at Aranesp.com
- · Follow your doctor's advice
- Take all your prescription medicines as they are prescribed

Remember, talk with your doctor before you make any changes to your treatment or lifestyle.

Using Aranesp[®] can lead to death or other serious side effects. If you decide to take Aranesp[®], your healthcare provider should prescribe the smallest dose that is necessary to reduce your chance of needing red blood cell transfusions.



18

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Please see accompanying Aranesp[®] <u>full prescribing information</u>, including **Boxed WARNINGS**, and Medication Guide.

