



MIRCERA
methoxy polyethylene glycol-epoetin beta



TREATING YOUR ANEMIA WITH MIRCERA®

Mircera is a prescription medicine for the treatment of your anemia caused by chronic kidney disease.

- Mircera works like the hormone erythropoietin to help your body make more red blood cells (RBCs). This can reduce or avoid the need for RBC transfusions.
- If you are on hemodialysis, Mircera will be given during your dialysis session.
- If you receive dialysis at home, please work with your dialysis provider to understand the appropriate way to take Mircera. Be sure that you read, understand, and follow the “Instructions for Use” that come with Mircera.

Mircera is not used:

- in the treatment of anemia that is caused by cancer chemotherapy.
- in place of emergency treatment for anemia (RBC transfusions).

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

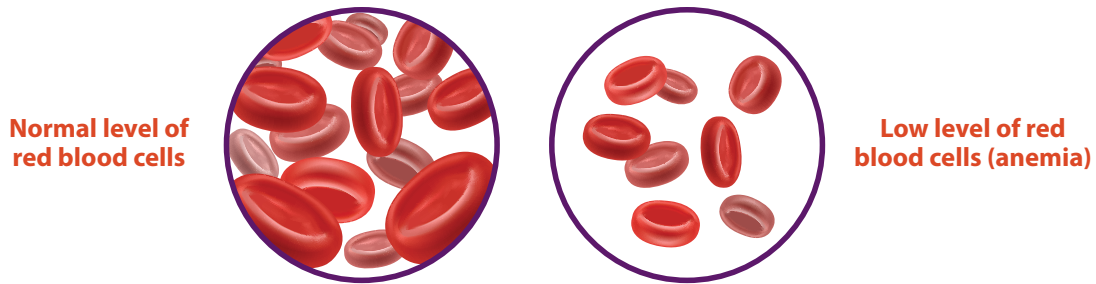
Please see **Important Safety Information** including serious side effects on pages 4-6, full **Prescribing Information**, including **Boxed WARNING, Medication Guide and Instructions for Use**.



What is anemia?*

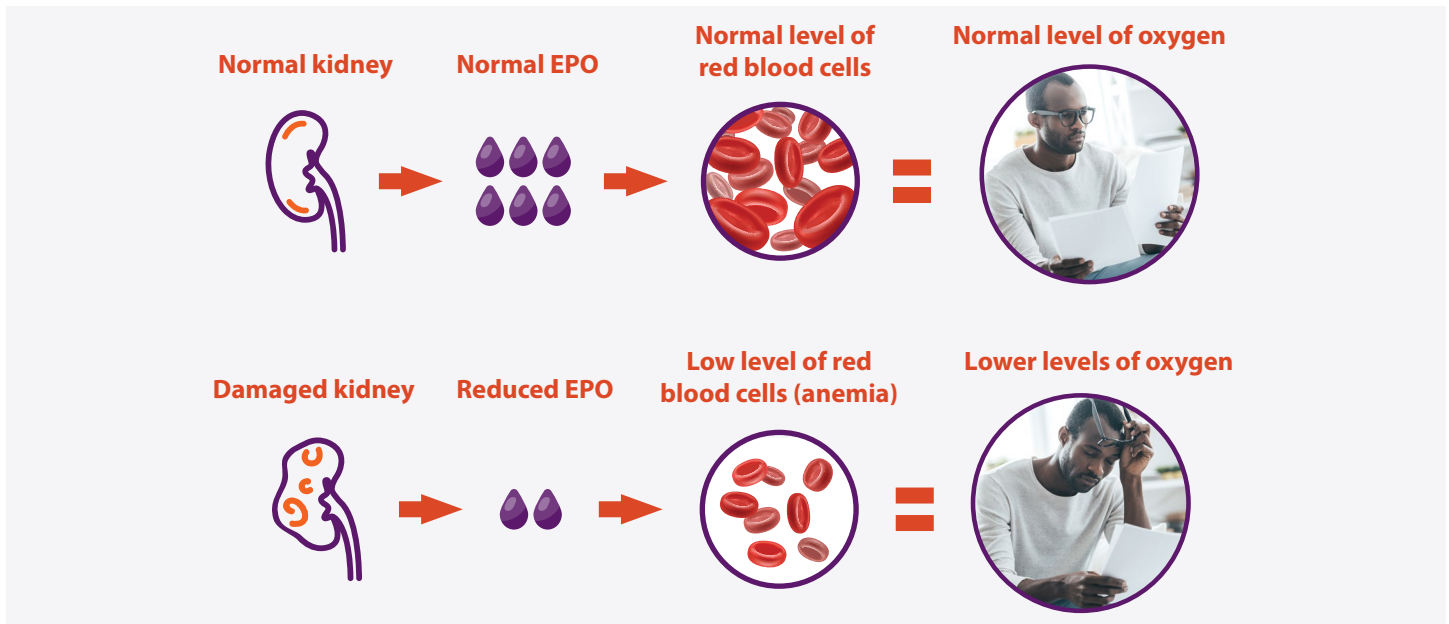
People with anemia have a lower than normal number of healthy red blood cells (RBCs). RBCs are important because they carry oxygen to the entire body. When RBCs are low in number, the body doesn't get enough oxygen, and people may start to feel tired, look pale, or feel short of breath.

Iron is needed to make RBCs, so you may be prescribed iron supplements. In instances when your anemia is very severe, you might need to receive a blood transfusion which can quickly increase the number of RBCs in your body.



Anemia and Chronic Kidney Disease*

Erythropoietin (EPO) is a hormone that enables red blood cell production. People with kidney disease may produce less EPO. You may be prescribed a medication called an erythropoiesis-stimulating agent (ESA) to increase the level of EPO in your body.



*National Kidney Foundation. Anemia and Chronic Kidney Disease. 2015. https://www.kidney.org/atoz/content/what_anemia_ckd. Accessed September 19, 2019.

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What is Mircera?

Mircera is a prescription medicine used for the treatment of anemia related to chronic kidney disease (CKD). Mircera works like the human hormone called erythropoietin to help your body make more RBCs. Mircera is used to reduce or avoid the need for RBC transfusions.

Mircera may be used to treat CKD-related anemia in:

- adults who may or may not be on hemodialysis, **and**
- children ages 5 to 17 years on hemodialysis.

Mircera is not used:

- in the treatment of anemia that is caused by cancer chemotherapy.
- in place of emergency treatment for anemia (RBC transfusions).

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

It is not known if Mircera is safe and effective in children:

- for subcutaneous use
- below the age of 5 years
- receiving peritoneal dialysis or who are not yet treated with dialysis
- whose anemia is not already controlled with another ESA

Is Mircera right for me?

Before you start Mircera, please tell your healthcare provider about all of your medical conditions, including if you:

- have heart disease.
- have or develop cancer.
- have high blood pressure.
- have had a seizure (convulsion) or stroke.
- receive dialysis treatment.
- are pregnant or plan to become pregnant. It is not known if Mircera may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Mircera passes into your breast milk.

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

Tell your healthcare provider if you have used Mircera in the past and had an allergic reaction.

Please see Important Safety Information including serious side effects on pages 4-6, full [Prescribing Information](#), including [Boxed WARNING](#), [Medication Guide](#) and [Instructions for Use](#).



How do I take Mircera?

Mircera is given intravenously or subcutaneously using a prefilled syringe.

If you receive hemodialysis, Mircera will be given during your dialysis session at the dialysis center.

If you receive dialysis at home, please work with your dialysis provider to understand the appropriate way to take Mircera. Be sure that you read, understand, and follow the "Instructions for Use" that come with Mircera. You can also find this information in the pamphlet "*Using Mircera® at Home: Instructions for Subcutaneous Injection*". If you have not received this document from your healthcare provider, please contact Vifor Pharma at 1-800-576-8295 or at mircera@viforpharma.com.

Possible serious side effects

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

For people with cancer:

- Mircera should not be used to treat anemia that is caused by cancer chemotherapy. If you have certain cancers, your tumor may grow faster and you may die sooner if you take Mircera.

For all people who take Mircera:

- **Serious heart problems, such as heart attack or heart failure, and stroke**

You may die sooner if you are treated with Mircera to increase RBCs to near the same level found in healthy people.

- **Blood clots**

Blood clots may happen at any time while taking Mircera. If you are receiving Mircera 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

Please see full Prescribing Information, including Boxed WARNING, Medication Guide and Instructions for Use for Mircera (methoxy polyethylene glycol-epoetin beta) Injection, for Intravenous or Subcutaneous Use.



Call your healthcare provider or get medical help right away if you have any of these symptoms (cont'd):

- Sudden trouble walking, dizziness, loss of balance or coordination
- Loss of consciousness (fainting)
- Hemodialysis vascular access stops working

Additional serious side effects

Mircera may cause other serious side effects including:

• **High blood pressure**

High blood pressure is a common side effect of Mircera in patients with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking Mircera. 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 Mircera, get medical help right away and tell your healthcare provider.

• **No response or loss of your hemoglobin response to Mircera**

If your hemoglobin does not increase, or if the increase cannot be maintained, your healthcare provider will look for the cause of the problem. Your dose of Mircera or other medicines may need to be changed.

• **Antibodies to Mircera**

Your body may produce antibodies to Mircera. 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 Mircera.

• **Serious allergic reaction**

Serious allergic reactions can cause 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 Mircera and call your healthcare provider or get emergency medical help right away.

• **Severe skin rash**

Severe skin rash can occur. If you develop a new rash, call your healthcare provider right away.

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Additional Important Safety Information

If you are recommended for treatment with Mircera, your healthcare provider should prescribe the smallest dose of Mircera that is necessary to reduce your chance of needing RBC transfusions.

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

Mircera should not be used if you:

- 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 Mircera or other erythropoiesis-stimulating agents.
- have had serious allergic reactions to Mircera.

Common side effects of Mircera include:

- Diarrhea
- Pain or swelling (inflammation) in your nose or throat (nasopharyngitis).

These are not all of the possible side effects of Mircera. 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.

Work together with your healthcare provider to manage your anemia and kidney disease

- Keep track of your lab test results, particularly your hemoglobin levels
- Take all your prescription medicines as directed
- **Follow your doctors' advice**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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