

MEDICATION GUIDE
MIRCERA® (mir-SER-ah)
(methoxy polyethylene glycol-epoetin beta)

Read this Medication Guide:

- before you start Mircera.
- if you are told by your healthcare provider that there is new information about Mircera.
- if you are told by your healthcare provider that you may inject Mircera 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 Mircera and ask if there is new information about Mircera.

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

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

For people with cancer:

- Mircera is not for use 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 red blood cells (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
- 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 Mircera?**" below for more information.

If you decide to take Mircera, your healthcare provider should prescribe the smallest dose of Mircera that is necessary to reduce your chance of needing RBC transfusions.

What is Mircera?

Mircera is a prescription medicine used to treat anemia. People with anemia have a lower-than-normal number of RBCs. Mircera works like the human protein 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 anemia if it is caused by chronic kidney disease (CKD) in:

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

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 is not used for 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
- not already on an erythropoiesis-stimulating agent (ESA) therapy.

Do not take Mircera 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 erythropoietin protein medicines.
- Have had serious allergic reactions to Mircera.

Before taking Mircera, 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.

How should I take Mircera?

- If you or your caregiver has been trained to give Mircera shots (injections) at home:
 - Be sure that you read, understand, and follow the "Instructions for Use" that come with Mircera.
 - Take Mircera exactly as your healthcare provider tells you to. Do not change the dose of Mircera unless told to by your healthcare provider.
 - Your healthcare provider will show you how much Mircera to use, how to inject it, how often it should be injected, and how to safely throw away the used prefilled syringes and needles.

- If you take more than your prescribed dose of Mircera, call your healthcare provider right away for instructions on what to do.
- During treatment with Mircera, continue to follow your healthcare provider's instructions for diet, dialysis, and medicines, including medicines for high blood pressure.
- Have your blood pressure checked as instructed by your healthcare provider.

What are possible side effects of Mircera?

Mircera may cause serious side effects, including:

- See **"What is the most important information I should know about Mircera?"**
- **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 make antibodies to Mircera. 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 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.

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.

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 Mircera?

- Store Mircera prefilled syringes in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze or shake Mircera.
- Keep Mircera in the original carton to protect from light.
- Mircera prefilled syringes may be stored at room temperature up to 77°F (25°C) for no more than 30 days. Throw away (discard) Mircera after 30 days.

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

General information about the safe and effective use of Mircera.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Mircera for a condition for which it was not prescribed. Do not give Mircera 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 Mircera that is written for health professionals.

What are the ingredients in Mircera?

Active ingredient: methoxy polyethylene glycol-epoetin beta

Inactive ingredients: mannitol, methionine, poloxamer 188, sodium phosphate monobasic monohydrate, and sodium sulfate.

Manufactured by:
Vifor (International) Inc.
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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