

MEDICATION GUIDE

MIRCERA® (mir-SER-ah)

(methoxy polyethylene glycol-epoetin beta)

Read this Medication Guide carefully before you start taking Mircera and each time you refill your Mircera prescription. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

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

Mircera stimulates your bone marrow to make more red blood cells. The increase in red blood cells also increases 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 problems include:

Serious heart problems. These problems include heart attack, stroke, and congestive heart failure.

Blood clots. Mircera treatment increases your chance of a blood clot. If you are scheduled for surgery, your healthcare provider may prescribe a blood thinner to prevent blood clots. Blood clots can form in your hemodialysis vascular access (such as arteriovenous fistulas) or in blood vessels, especially in the leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs. If this happens, blood circulation in the lungs may be blocked (pulmonary embolus).

Tell your healthcare provider or get medical attention right away if you have any of these symptoms while taking Mircera:

- Chest pain
- Trouble breathing or shortness of breath
- Pain in the legs, with or without swelling
- A cool or pale arm or leg
- Sudden confusion or trouble speaking or understanding speech
- Sudden numbness or weakness of the face, an arm or leg, especially on one side of the body
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance or coordination, loss of consciousness
- Sudden severe headache with no known cause
- Seizures (convulsions)
- Blood clots in your hemodialysis vascular access (such as arteriovenous fistulas).

It is important for you to have the blood tests ordered by your healthcare provider. Your healthcare provider will try to keep your hemoglobin level between 10 and 12 g/dL.

Mircera is not used to treat anemia caused by cancer chemotherapy. In patients with cancer, drugs that act like Mircera increase the chance of dying sooner or making the cancer grow faster. In a clinical study of cancer patients, more deaths occurred among patients receiving Mircera compared to another drug that also increases blood hemoglobin.

What is Mircera?

Mircera is a man-made form of the human protein erythropoietin. Erythropoietin is normally produced by the kidneys. Mircera and other man-made erythropoietins are ESAs (Erythropoiesis-Stimulating Agents). ESAs stimulate bone marrow to make red blood cells. The increase in red blood cells also increases the blood

hemoglobin level. Your healthcare provider will prescribe the lowest dose of Mircera needed to help increase your hemoglobin level to between 10 to 12 g/dL and to help avoid the need for red blood cell transfusions.

You may be asked to have certain blood tests, such as hemoglobin, hematocrit, or iron level measurements. Based on your test results, your healthcare provider will adjust the dose of Mircera as needed to reach the right dose for you and to help prevent serious side effects. The right dose for you may change over time.

Mircera is not used to treat anemia that is caused by other health problems, such as cancer.

Mircera has not been studied in children.

Who should not take Mircera?

Do not take Mircera if:

- You have high blood pressure that is not controlled (uncontrolled hypertension)
- You have allergies to Mircera or other ESAs
- You have anemia caused by cancer chemotherapy

What should I tell my healthcare provider before taking Mircera?

Mircera may not be right for you. 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 any history of stroke, blood clots or seizures
- Have blood disorders (such as sickle cell anemia or clotting disorders)
- Are pregnant, think you may be pregnant or plan to become pregnant. The effect of Mircera on pregnant women is unknown. It is also not known if Mircera could harm an unborn baby.
- Are breast-feeding or plan to breast-feed. It is not known if Mircera passes into human breast milk.

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

How should I take Mircera?

Mircera is taken as either an intravenous (IV) or subcutaneous (SC) injection. It can take two to six weeks of treatment to see an increase in your hemoglobin level. If the desired increase is not seen, your healthcare provider may change your treatment dose.

- Mircera should be administered by your healthcare provider. In some cases, your healthcare provider may allow you or your caregiver to give the injections at home.
- If you or your caregiver are allowed to give the injections at home, it is important that you carefully follow the instructions that your healthcare provider gives you. Be sure that you read, understand, and follow the "Patient Instructions for Use."
- 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 or your caregiver how much Mircera to use, how to inject it, how often it should be injected and how to safely throw away used needles and syringes.

- Change the skin site for each injection to avoid soreness at any one site. Sometimes a problem may develop at the injection site. If there is a lump, swelling, or bruising at the injection site that does not go away, talk to your healthcare provider.

- **To use Mircera safely at home, it is important that you:**

- Use the contents of a vial or prefilled syringe one time only
- Throw away any solution remaining in the vial after use
- Use a needle and syringe only one time for injection

- If you have a hemodialysis vascular access, regularly check it to make sure it is working. Call your healthcare provider or dialysis center right away if you have any problems or questions.

- If you miss one dose of Mircera, take your dose right away and then continue as you have been told by your healthcare provider. If you miss more than one dose, call your healthcare provider right away for instructions on what to do.

- If you take more than the prescribed amount of Mircera, call your healthcare provider right away for instructions on what to do.

- Continue to follow your healthcare provider's instructions for diet, dialysis, and medicines including medicines for high blood pressure, while taking Mircera.

What are possible side effects of Mircera?

Mircera can cause serious side effects. See "**What is the most important information I should know about Mircera?**"

Other side effects, which may be serious include:

- **High blood pressure.** Your blood pressure may go up when the numbers of red blood cells increase while taking Mircera. This can happen even if you have never had high blood pressure before. Your healthcare provider or caregiver should check your blood pressure often. If you have a history of heart problems or high blood pressure, talk with your healthcare provider about how often to check your blood pressure. Call your healthcare provider if your blood pressure changes from what is normal for you. If your blood pressure does increase, your healthcare provider may prescribe new or more blood pressure medicine.
- **Seizures.** Seizures can occur in people receiving Mircera. If you have any seizures while taking Mircera, get medical help right away and tell your healthcare provider.
- **Serious allergic reaction.** Mircera may cause a serious allergic reaction. Symptoms of a serious allergic reaction may include: a rash all over the body, shortness of breath, wheezing, dizziness, fainting, swelling around the mouth or eyes, fast pulse, or sweating. If a serious allergic reaction occurs, stop using Mircera and call your healthcare provider or get emergency medical help right away.
- **No response or loss of your hemoglobin response to Mircera.** If your hemoglobin does not reach the desired level of 10 to 12 g/dL or your hemoglobin does not stay within this level, 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 reduce 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.

The most common side effects you may have when taking Mircera are:

- Increased blood pressure (hypertension)
- Diarrhea

- Upper respiratory tract infections (cold, cough and sinus infections)
- Headache

Other side effects when taking Mircera may include:

- Decreased blood pressure (hypotension)
- Vomiting
- Constipation
- Urinary tract infections
- Body or muscle aches, including back pain
- Swelling in your arms or legs with or without shortness of breath
- Problems with your hemodialysis vascular access (such as arteriovenous fistulas), including clotting and fistula site problems
- Injection site reactions such as redness, swelling, or itching. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Mircera. Your healthcare provider or pharmacist can give you a more complete list.

How should I store Mircera?

- Keep Mircera in the original package. Protect Mircera from light. Do not use Mircera that has been left in bright light.
- Do not shake Mircera
- Store Mircera in the refrigerator at 36°F to 46°F (2°C to 8°C)
- If a refrigerator is not available, Mircera Prefilled Syringes can be stored at room temperature 77°F or less (25°C or less) for up to 30 days
- Mircera Vials can be stored at room temperature 77°F or less (25°C or less) for up to 7 days
- Do not freeze Mircera. Do not use Mircera that has been frozen or improperly refrigerated. Talk to your healthcare provider or pharmacist with any questions about storing Mircera.

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

General Information about 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. This Medication Guide summarizes the most important information about Mircera. If you would like to know more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Mircera that is written for health professionals. For more information, go to www.MIRCERA.com OR call 1-800-526-6367.

What are the ingredients in Mircera?

Active ingredient: methoxy polyethylene glycol-epoetin beta

Inactive ingredients: sodium phosphate, sodium sulphate, mannitol, methionine and poloxamer 188

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

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

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