

MEDICATION GUIDE

Epogen® (Ee-po-jen) (epoetin alfa)

Read this Medication Guide before you start Epogen, each time you refill your prescription, and if you are told by your healthcare provider that there is new information about Epogen. 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 Epogen and ask if there is new information about Epogen.

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

Using Epogen can lead to death or other serious side effects.

Patients with cancer:

Your healthcare provider has received special training through the ESA APPRISE Oncology Program in order to prescribe Epogen. Before you can begin to receive Epogen, you must sign the ESA APPRISE Oncology Patient and Healthcare Professional (HCP) Acknowledgement Form to document that your healthcare provider discussed the risks of Epogen with you. When you sign this form, you are stating that you are aware of the risks associated with use of Epogen.

These risks include that your tumor may grow faster and you may die sooner when Epogen is used experimentally to try to raise your hemoglobin beyond the amount needed to avoid red blood cell transfusion or if you are not getting strong doses of chemotherapy. It is not known whether these risks exist when Epogen is given according to the FDA-approved directions for use.

You should discuss with your doctor:

- Why Epogen treatment is being prescribed.
- What are the chances you will get red blood cell transfusions if you do not take Epogen.
- What are the chances you will get red blood cell transfusions even if you take Epogen.
- How taking Epogen may affect the success of your cancer treatment.

If you decide to take Epogen, your healthcare provider should prescribe the smallest dose of Epogen to lower the chance of getting red blood cell transfusions.

- After you have finished your chemotherapy course, Epogen treatment should be stopped.
- Epogen does not improve the symptoms of anemia (lower than normal number of red blood cells), quality of life, fatigue, or well-being for patients with cancer.

All patients, including patients with cancer or chronic kidney failure:

- You may get serious heart problems such as heart attack, stroke, heart failure, and may die sooner if you are treated with Epogen to a hemoglobin level above 12 g/dL.
- You may get blood clots at any time while taking Epogen. If you are receiving Epogen 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. 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 of blood clots:

- 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. If you are a patient with chronic kidney failure and have a hemodialysis vascular access, blood clots may form in this access.

Also see **“What are the possible side effects of Epogen?”** below.

What is Epogen?

Epogen is a man-made form of the protein human erythropoietin that is given to patients to lessen the need for red blood cell transfusions. Epogen stimulates your bone marrow to make more red blood cells. Having more red blood cells raises 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 serious health problems may happen even if you take Epogen and do not have an increase in your hemoglobin level.

Epogen may be used to treat a lower than normal number of red blood cells (anemia) if it is caused by:

- Chronic kidney failure (you may or may not be on dialysis)
- Chemotherapy that is used for at least two months to treat some types of cancer
- A medicine called zidovudine (AZT) used to treat HIV infection

Epogen may also be used if you are scheduled for certain surgeries with a lot of blood loss to reduce the chance you will need red blood cell transfusions.

Epogen should not be used for treatment of anemia:

- In place of emergency treatment (red blood cell transfusions)
- If you have cancer and you are not receiving chemotherapy that may cause anemia
- If your cancer has a high chance of being cured

Epogen should not be used if you are scheduled for certain surgeries and you are able and willing to donate blood prior to surgery.

Who should not take Epogen?

Do not take Epogen if you:

- Have cancer and have not been counseled by your healthcare provider regarding the risks of Epogen and signed the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgement Form before you begin to receive Epogen.
- 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 Epogen or other erythropoietin medicines.

- Have allergies to any of the ingredients in Epogen. See the end of this Medication Guide for a complete list of ingredients in Epogen.

Do not give Epogen from multidose vials to premature babies.

What should I tell my healthcare provider before taking Epogen?

Epogen may not be right for you. **Tell your healthcare provider about all your health conditions**, including if you:

- Have heart disease.
- Have high blood pressure.
- Have had a seizure (convulsion) or stroke.
- Are pregnant or planning to become pregnant. It is not known if Epogen may harm your unborn baby. Talk with your healthcare provider about possible pregnancy and birth control choices that are right for you.
- Are breast-feeding or planning to breast-feed. It is not known if Epogen passes into breast milk.

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

Know the medicines you take. Keep a list of your medicines with you and show it to your healthcare provider when you get a new medicine.

How should I take Epogen?

Patients with cancer:

Before you begin to receive Epogen, your healthcare provider will:

- Ask you to review this Epogen Medication Guide
- Explain the risks of Epogen and answer all your questions about Epogen
- Have you sign the ESA APPRISE Oncology Program Patient and Healthcare Professional (HCP) Acknowledgement Form

All patients:

- Continue to follow your healthcare provider's instructions for diet, dialysis, and medicines, including medicines for high blood pressure, while taking Epogen.
- Have your blood pressure checked as instructed by your healthcare provider.
- If you or your caregiver has been trained to give Epogen shots (injections) at home:
 - Be sure that you read, understand, and follow the "Patient Instructions for Use" that come with Epogen.
 - Take Epogen exactly as your healthcare provider tells you to. Do not change the dose of Epogen unless told to do so by your healthcare provider.
 - Your healthcare provider will show you how much Epogen to use, how to inject it, how often it should be injected, and how to safely throw away the used vial, syringes, and needles.
 - If you miss a dose of Epogen, call your healthcare provider right away and ask what to do.
 - If you take more than the prescribed amount of Epogen, call your healthcare provider right away.

What are the possible side effects of Epogen?

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

Other side effects of Epogen, which may also be serious, include:

- **High blood pressure in patients with chronic kidney failure.** Your blood pressure may go up or be difficult to control with blood pressure medicine while taking Epogen. 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 Epogen, get medical help right away and tell your healthcare provider.
- **Antibodies to Epogen.** Your body may make antibodies to Epogen. 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 Epogen.
- **Serious allergic reactions.** Serious allergic reactions can cause a rash over your whole body, 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 Epogen and call your healthcare provider or get medical help right away.
- **Dangers of giving Epogen to premature babies.** Epogen from multi-dose vials contain benzyl alcohol. Do not give Epogen from multidose vials to premature babies because it can cause death and brain damage.

Common side effects of Epogen include:

- Rash
- Swelling in your legs and arms
- Injection site reaction, including irritation and pain

These are not all of the possible side effects of Epogen. 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 Epogen?

- Store Epogen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze.** Do not use a vial of Epogen that has been frozen.
- Keep away from direct light.
- Do not shake Epogen.
- Throw away multidose vials of Epogen after 21 days from the first day that you put a needle into the vial.
- Single use vials of Epogen should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

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

General information about Epogen

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use Epogen only for the condition for which it has been prescribed. Do not give Epogen 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 Epogen. If you would like more information about Epogen, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for

information about Epogen that is written for healthcare professionals. For more information, go to the following website: www.epogen.com or call 1-800-77-AMGEN.

What are the ingredients in Epogen?

Active Ingredient: epoetin alfa

Inactive Ingredients: All formulations include albumin (human), sodium citrate, sodium chloride, and citric acid in Water for Injection. Multidose vials contain benzyl alcohol. Certain formulations also contain sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrate.



Manufactured by:

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.
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Revised:

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