

MEDICATION GUIDE

Epogen® (Ee-po-jen)
(epoetin alfa)

Read this Medication Guide:

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

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

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

For people with cancer:

- Your tumor may grow faster and you may die sooner if you choose to take Epogen. Your healthcare provider will talk with you about these risks.

For all people who take Epogen, 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 Epogen 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 Epogen. If you are receiving Epogen 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 Epogen?**" below for more information.

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

What is Epogen?

Epogen is a prescription medicine used to treat anemia. People with anemia have a lower-than-normal number of RBCs. Epogen works like the human protein called erythropoietin to help your body make more RBCs. Epogen is used to reduce or avoid the need for RBC transfusions.

Epogen may be used to treat anemia if it is caused by:

- Chronic kidney disease (you may or may not be on dialysis).
- Chemotherapy that will be used for at least two months after starting Epogen.
- A medicine called zidovudine (AZT) used to treat HIV infection.

Epogen may also be used to reduce the chance you will need RBC transfusions if you are scheduled for certain surgeries where a lot of blood loss is expected.

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

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

Epogen **should not be used** for treatment of anemia:

- If you have cancer and you will not be receiving chemotherapy that may cause anemia.
- If you have a cancer that has a high chance of being cured. Talk with your healthcare provider about the kind of cancer you have.
- If your anemia caused by chemotherapy treatment can be managed by RBC transfusion.
- In place of emergency treatment for anemia (RBC transfusions).

Epogen should not be used to reduce the chance you will need RBC transfusions if:

- You are scheduled for surgery on your heart or blood vessels.
- You are able and willing to donate blood prior to surgery.

It is not known if Epogen is safe and effective in treating anemia in children less than 1 month old who have chronic kidney disease and in children less than 5 years old who have anemia caused by chemotherapy.

Who should not take Epogen?

Do not take Epogen if you:

- Have cancer and have not been counseled by your healthcare provider about treatment with 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 protein medicines.
- Have had a serious allergic reaction to Epogen.

Do not give Epogen from multiple-dose vials to:

- Pregnant or breastfeeding women
- Babies

Before taking EPOGEN, tell your healthcare provider about all of your medical conditions, including if you:

- Have heart disease.
- 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 Epogen may harm your unborn baby. Talk to your healthcare provider about possible pregnancy and birth control choices that are right for you.
- Are breastfeeding or plan to breastfeed. It is not known if Epogen passes into breast milk.

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

How should I take Epogen?

- If you or your caregiver has been trained to give Epogen shots (injections) at home:
 - Be sure that you read, understand, and follow the "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 vials, 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 dose of Epogen, call your healthcare provider right away.
- During treatment with Epogen, continue to follow your healthcare provider's instructions for diet and medicines.
- Have your blood pressure checked as instructed by your healthcare provider.

What are the possible side effects of Epogen?

Epogen may cause serious side effects, including:

- See “**What is the most important information I should know about Epogen?**”
- **High blood pressure.** High blood pressure is a common side effect of Epogen in people with chronic kidney disease. 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 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 Epogen.
- **Serious allergic reactions.** Serious allergic reactions can cause a skin rash, 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 Epogen and call your healthcare provider or get medical help right away.
- **Severe skin reactions.** Signs and symptoms of severe skin reactions with Epogen may include: skin rash with itching, blisters, skin sores, peeling, or areas of skin coming off. If you have any signs or symptoms of a severe skin reaction, stop using Epogen and call your healthcare provider or get medical help right away.
- **Dangers of using Epogen from multiple-dose vials in newborns, infants, and pregnant or breastfeeding women.** Do not use Epogen from multiple-dose vials in newborns, infants, pregnant or breastfeeding women because the Epogen in these vials contains benzyl alcohol. Benzyl alcohol has been shown to cause brain damage, other serious side effects, and death in newborn and premature babies. If you use Epogen from multiple-dose vials you should not breastfeed for at least 2 weeks after the last dose. Epogen that comes in single-dose vials does not contain benzyl alcohol. See “**Who should not take Epogen?**”

Common side effects of Epogen include:

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| • joint, muscle, or bone pain | • rash | • soreness of mouth |
| • fever | • nausea | • itching |
| • cough | • vomiting | • headache |
| • dizziness | • blood vessel blockage | • respiratory infection |
| • high blood sugar | • low white blood cells | • weight decrease |
| • low potassium levels in the blood | • trouble sleeping | • depression |
| • chills | • difficulty swallowing | • muscle spasm |
| • redness and pain at the Epogen injection site | | |

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?

- Do not shake Epogen.
- Store Epogen vials in the carton it comes in to protect from light.
- Store Epogen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze Epogen.** Do not use Epogen that has been frozen.
- Throw away multiple-dose vials of Epogen no later than 21 days from the first day that you put a needle into the vial.
- Single-dose 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. Do not use Epogen for a condition for which it was not prescribed. Do not give Epogen 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 Epogen that is written for healthcare professionals.

What are the ingredients in Epogen?

Active ingredient: epoetin alfa

Inactive ingredients:

- Multiple-dose vials contain benzyl alcohol.
- All vials contain albumin (human), citric acid, sodium chloride, sodium citrate, and Water for Injection.

Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, CA 91320-1799 U.S.A.

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For more information, go to the following website: www.epogen.com or call 1-800-77-AMGEN

The logo for Amgen, featuring the word "AMGEN" in a bold, black, sans-serif font with a registered trademark symbol (®) to the upper right.

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

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