

FDA Approved: 11-19-08

MEDICATION GUIDE

PROCRIT® (PRO'-KRIT) (epoetin alfa)

Read this Medication Guide before you start PROCRT, each time you refill your prescription, and if you are told by your healthcare provider that there is new information about PROCRT. This Medication Guide was revised August 2008. 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 PROCRT and ask if there is new information about PROCRT.

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

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

Patients with cancer:

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

You should discuss with your doctor:

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

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

- After you have finished your chemotherapy course, PROCRT treatment should be stopped.
- PROCRT 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 PROCRT to a hemoglobin level above 12 g/dL.
- You may get blood clots at any time while taking PROCRT. If you are receiving PROCRT 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 PROCRIT?**” below.

What is PROCRIT?

PROCRIT is a man-made form of the protein human erythropoietin that is given to patients to lessen the need for red blood cell transfusions. PROCRIT 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 PROCRIT and do not have an increase in your hemoglobin level.

PROCRIT 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

PROCRIT 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.

Who should not take PROCRIT?

Do not take PROCRIT if you:

- Have high blood pressure that is not controlled (uncontrolled hypertension).
- Have allergies to any of the ingredients in PROCRIT. See the end of this Medication Guide for a complete list of ingredients in PROCRIT.

What should I tell my healthcare provider before taking PROCRIT?

PROCRIT 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 PROCRIT may harm your unborn baby.
- Are breast-feeding or planning to breast-feed. It is not known if PROCRIT passes into breast milk.
- Women who do not have regular monthly menstrual periods may begin to have monthly periods while taking PROCRIT. Talk with your doctor about the possibility of pregnancy while taking PROCRIT.

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 PROCRIT?

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

What are the possible side effects of PROCRIT?

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

Other side effects of PROCRIT, 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 medicines while taking PROCRIT. 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 PROCRIT, get medical help right away and tell your healthcare provider.
- **Antibodies to PROCRIT.** Your body may make antibodies to PROCRIT. 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 PROCRIT.
- **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 PROCRIT and call your healthcare provider or get medical help right away.
- **Dangers of giving PROCRIT to premature babies.** PROCRIT from multidose vials that contain benzyl alcohol should not be given to premature babies because it can cause death and brain damage.

Common side effects of PROCRIT 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 PROCRIT. 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 PROCRIT?

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

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

General information about PROCRIT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use PROCRIT only for the condition for which it has been prescribed. Do not give PROCRIT 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 PROCRIT. If you would like more information about PROCRIT, talk to your healthcare provider. You can ask your healthcare provider or pharmacist for information about PROCRIT that is written for healthcare professionals. For more information, go to the following website: www.PROCRIT.com or call 1 888 2ASK OBI or 1-888-227-5624.

What are the ingredients in PROCRIT?

Active Ingredient: epoetin alfa

Inactive Ingredients: All formulations include albumin (human), sodium citrate, sodium chloride, and citric acid in water for injection. Multi-use vials contain benzyl alcohol. Certain formulations also contain sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrate.

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

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