What is PROCRIT?

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

PROCRIT 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 PROCRIT.
• A medicine called zidovudine (AZT) used to treat HIV infection.

PROCRIT 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 PROCRIT, even if you do not have an increase in your hemoglobin level. PROCRIT has not been proven to improve quality of life, fatigue, or well-being.

PROCRIT 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).

PROCRIT 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 PROCRIT 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 PROCRIT?

Do not take PROCRIT if you:
• Have cancer and have not been counseled by your healthcare provider about treatment with PROCRIT.
• 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 PROCRIT or other erythropoietin protein medicines.
• Have had a serious allergic reaction to PROCRIT.
Do not give PROCRIT from multiple-dose vials to:

- Pregnant or breastfeeding women
- Babies

Before taking PROCRIT, 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 PROCRIT 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 PROCRIT 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 PROCRIT?

- If you or your caregiver has been trained to give PROCRIT shots (injections) at home:
  ○ Be sure that you read, understand, and follow the "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 vials, 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 dose of PROCRIT, call your healthcare provider right away.
- During treatment with PROCRIT, 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 PROCRIT?

PROCRIT may cause serious side effects, including:

- See "What is the most important information I should know about PROCRIT?"
- **High blood pressure.** High blood pressure is a common side effect of PROCRIT in people with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine 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 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 PROCRIT.
- **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 PROCRIT and call your healthcare provider or get medical help right away.
- **Severe skin reactions.** Signs and symptoms of severe skin reactions with PROCRIT 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 PROCRIT and call your healthcare provider or get medical help right away.
- **Dangers of using PROCRIT from multiple-dose vials in newborns, infants, and pregnant or breastfeeding women.** Do not use PROCRIT from multiple-dose vials in newborns, infants, pregnant or breastfeeding women because the PROCRIT 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 PROCRIT from multiple-dose vials you should not breastfeed for at least 2 weeks after the last dose. PROCRIT that comes in single-dose vials does not contain benzyl alcohol. See "Who should not take PROCRIT?"

Common side effects of PROCRIT include:

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

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?**

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

**What are the ingredients in PROCRIT?**

**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.
- Single-dose vials containing 40,000 Units of PROCRIT also contain sodium phosphate dibasic anhydrate and sodium phosphate monobasic monohydrate.

**Manufactured by:**

Amgen Inc.
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**Manufactured for:**

Janssen Products, LP
Horsham, Pennsylvania 19044

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For more information, go to the following website:
www.PROCRIT.com or call 1-800-JANSSEN (1-800-526-7736).

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