

PROCRIT® (epoetin alfa) What Are the Possible Side Effects of PROCRIT?

SUMMARY

Here is a passage from the PROCRIT MEDICATION GUIDE, which may be helpful in addressing your question:

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

PROCRIT may cause serious side effects that can lead to death, including¹:

For people with cancer¹:

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

For all people who take PROCRIT, including people with cancer or chronic kidney disease¹:

- **Serious heart problems, such as heart attack or heart failure, and stroke.** You may die sooner if you are treated with PROCRIT to increase red blood cells (RBCs) to near the same level found in healthy people.¹
- **Blood clots.** Blood clots may happen at any time while taking PROCRIT. If you are receiving PROCRIT 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).¹
- Call your healthcare provider or get medical help right away if you have any of these symptoms¹:
 - 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 decide to take PROCRIT, your healthcare provider should prescribe the smallest dose of PROCRIT that is necessary to reduce your chance of needing RBC transfusions.¹

What are the possible side effects of PROCRIT?

PROCRIT may cause serious side effects, including the following:

- **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.¹
- **Seizures.** If you have any seizures while taking PROCRIT, get medical help right away and tell your healthcare provider.¹

- **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.¹
- **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.¹
- **Severe skin reactions.** Signs and symptoms of severe skin reactions with PROCRIT may include skin rash with itching, blisters, skin sores, and 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.¹
- **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.¹

Common side effects of PROCRIT include¹:

- 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 PROCRIT injection site
- These are not all 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.¹
 - Call your doctor for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.¹

ADDITIONAL INFORMATION

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical

treatment should be made with your healthcare professional(s). Please contact your healthcare team(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and the MEDICATION GUIDE for PROCRIT.^{1,2}

REFERENCE

1. PROCRIT (epoetin alfa) [Medication Guide]. Horsham, PA: Janssen Products, LP;
<https://www.janssenlabels.com/package-insert/product-patient-information/PROCRIT-medication-guide.pdf>.

2. PROCRIT (epoetin alfa) [Prescribing Information]. Horsham, PA: Janssen Products, LP;
<https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf>