

MEDICATION GUIDE
PROCRIT® (PRO'-KRIT)
(epoetin alfa)

Read this Medication Guide:

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

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

PROCRIT 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 PROCRIT. Your healthcare provider will talk with you about these risks.

For all people who take PROCRIT, 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 PROCRIT 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 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).
- 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 PROCRIT?"** below for more information.

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.

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 PROCRI[®]?

- If you or your caregiver has been trained to give PROCRI[®] shots (injections) at home:
 - Be sure that you read, understand, and follow the “Instructions for Use” that come with PROCRI[®].
 - Take PROCRI[®] exactly as your healthcare provider tells you to. Do not change the dose of PROCRI[®] unless told to do so by your healthcare provider.
 - Your healthcare provider will show you how much PROCRI[®] 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 PROCRI[®], call your healthcare provider right away and ask what to do.
 - If you take more than the prescribed dose of PROCRI[®], call your healthcare provider right away.
- During treatment with PROCRI[®], 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 PROCRI[®]?

PROCRI[®] may cause serious side effects, including:

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

Common side effects of PROCRI[®] include:

- | | | |
|--|-------------------------|-------------------------|
| • 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 PROCRI [®] injection site | | |

These are not all of the possible side effects of PROCRI[®]. 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 PROCRT?

- Do not shake PROCRT.
- Store PROCRT vials in the carton it comes in to protect from light.
- Store PROCRT in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze PROCRT.** Do not use PROCRT that has been frozen.
- Throw away multiple-dose vials of PROCRT no later than 21 days from the first day that you put a needle into the vial.
- Single-dose vials of PROCRT should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

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

General information about PROCRT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PROCRT for a condition for which it was not prescribed. Do not give PROCRT 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 PROCRT that is written for healthcare professionals.

What are the ingredients in PROCRT?

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 PROCRT also contain sodium phosphate dibasic anhydrate and sodium phosphate monobasic monohydrate.

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Manufactured for:

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

Instructions for Use
PROCRIT® (PRO-KRIT)
(epoetin alfa)

Use these Instructions for Use if you or your caregiver has been trained to give PROCRIT injections at home. Do not give yourself the injection unless you have received training from your healthcare provider. If you are not sure about giving the injection or you have questions, ask your healthcare provider for help.

Before reading these Instructions for Use, read the Medication Guide that comes with PROCRIT for the most important information you need to know.

When you receive your PROCRIT vial and syringes make sure that:

- The name PROCRIT appears on the carton and vial label.
- The expiration date on the vial label has not passed. Do not use a vial of PROCRIT after the expiration date on the label.
- The dose strength of the PROCRIT vial (number of Units per mL on the vial label) is the same as your healthcare provider prescribed.
- You understand what the dose strength of PROCRIT means. PROCRIT vials come in several dose strengths. For example, the dose strength may be described as 10,000 Units/mL on the vial label. This strength means that 10,000 Units of medicine are contained in each 1 mL (milliliter) of liquid. Your healthcare provider may also refer to a mL as a “cc.” One mL is the same as one “cc.”
- The PROCRIT liquid in the vial is clear and colorless. Do not use PROCRIT if the liquid in the vial looks discolored or cloudy, or if the liquid has lumps, flakes, or particles.
- The PROCRIT vial has a color cap on the top of the vial. Do not use a vial of PROCRIT if the color cap on the top of the vial has been removed or is missing.
- Use only the type of disposable syringe and needle that your healthcare provider has prescribed.
- Do not shake PROCRIT. Shaking could cause PROCRIT not to work. If you shake PROCRIT, the solution in the vial may look foamy and should not be used.
- Do not freeze PROCRIT. Do not use a vial of PROCRIT that has been frozen.
- Store PROCRIT in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep PROCRIT away from light.
- 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.
- After removing a dose from the multidose vial, store the vial in the refrigerator (but not the freezer). Do not store the vial for more than 21 days.
- Throw away the multidose vial as directed by your healthcare provider:
 - if there is not enough medicine left in the multidose vial for another dose, **or**
 - if it has been more than 21 days since you first put a needle into the multidose vial.

How should I prepare for an injection of PROCRIT?

- Always keep an extra syringe and needle on hand.
- Follow your healthcare provider’s instructions on how to measure your dose of PROCRIT. This dose will be measured in Units per mL or cc (1 mL is the same as 1 cc). Use a syringe that is marked in tenths of mL (for example, 0.2 mL or 0.2 cc). Using the wrong syringe can lead to a mistake in your dose and you could inject too much or too little PROCRIT.

Only use disposable syringes and needles. Use the syringes and needles only one time and then throw them away as instructed by your healthcare provider.

What do I need to know about the different types of PROCRIT vials?

PROCRIT comes in two different types of vials.

- Single-dose Vials
- Multidose Vials

The multidose vial of PROCRIT contains the preservative benzyl alcohol. Benzyl alcohol has been shown to cause brain damage, other serious side effects, and death in newborn and premature babies. PROCRIT that comes in single-dose vials does not contain benzyl alcohol.

Important: Follow these instructions exactly to help avoid infections.

Preparing the dose:

1. Remove the vial of PROCRIT from the refrigerator. During this time, protect the solution from light.
2. Do not use a single-dose vial of PROCRIT more than one time.
3. Do not shake PROCRIT.
4. Gather the other supplies you will need for your injection (vial, syringe, alcohol wipes, cotton ball, and a puncture-proof container for throwing away the syringe and needle). See Figure 1.

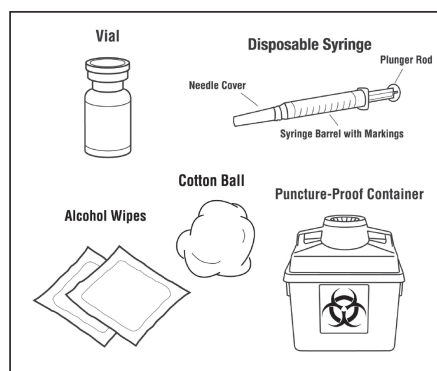


Figure 1

5. Check the date on the PROCRIT vial to be sure that the drug has not expired.

- Wash your hands well with soap and water before preparing the medicine. See Figure 2.



Figure 2

- Flip off the protective color cap on the top of the vial. Do not remove the grey rubber stopper. Wipe the top of the grey rubber stopper with an alcohol wipe. See Figures 3 and 4.

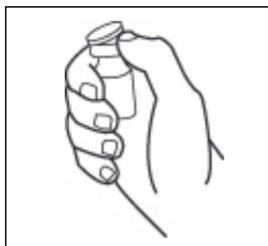


Figure 3

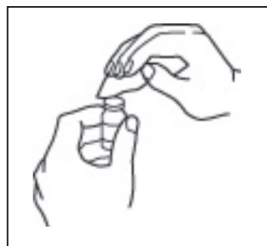


Figure 4

- Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Throw away the syringe in the puncture-proof disposable container. If the syringe package is undamaged, open the package and remove the syringe.
- Using a syringe and needle that has been recommended by your healthcare provider, carefully remove the needle cover. See Figure 5. Then draw air into the syringe by pulling back on the plunger. The amount of air drawn into the syringe should be equal to the amount (mL or cc) of the PROCrit dose prescribed by your healthcare provider. See Figure 6.

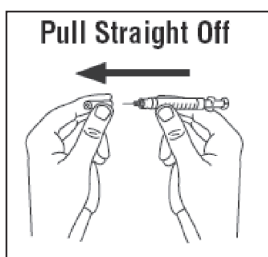


Figure 5

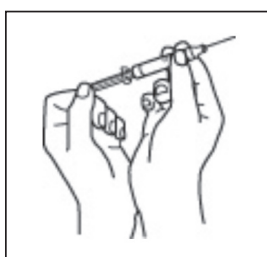


Figure 6

- With the vial on a flat work surface, insert the needle straight down through the grey rubber stopper of the PROCrit vial. See Figure 7.

- Push the plunger of the syringe down to inject the air from the syringe into the vial of PROCrit. The air injected into the vial will allow PROCrit to be easily withdrawn into the syringe. See Figure 7.

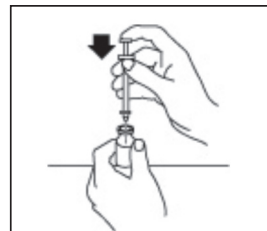


Figure 7

- Keep the needle inside the vial. Turn the vial and syringe upside down. Be sure the tip of the needle is in the PROCrit liquid. Keep the vial upside down. Slowly pull back on the plunger to fill the syringe with PROCrit liquid to the number (mL or cc) that matches the dose your healthcare provider prescribed. See Figure 8.

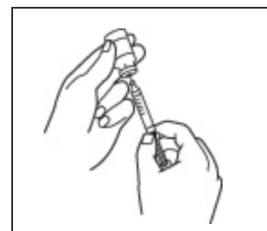


Figure 8

- Keep the needle in the vial. Check for air bubbles in the syringe. A small amount of air is harmless. Too large an air bubble will give you the wrong PROCrit dose. To remove air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe. Keep the tip of the needle in the PROCrit liquid. Pull the plunger back to the number on the syringe that matches your dose. Check again for air bubbles. If there are still air bubbles, repeat the steps above to remove them. See Figures 9 and 10.

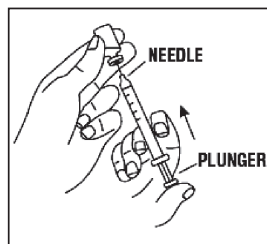


Figure 9

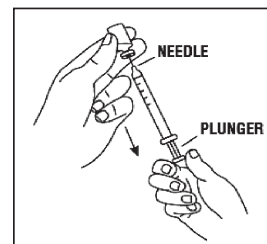


Figure 10

- Double-check that you have the correct dose in the syringe. Lay the vial down on its side with the needle still in it until after you have selected and prepared your site for injection.

Selecting and preparing the injection site:

PROCRI[®] can be injected into your body using two different ways (routes) as described below. Follow your healthcare provider's instructions about how you should inject PROCRI[®]. In patients on hemodialysis, the intravenous (IV) route is recommended.

1. Subcutaneous Route:

- PROCRI[®] can be injected directly into a layer of fat under your skin. This is called a subcutaneous injection. When giving subcutaneous injections, follow your healthcare provider's instructions about changing the site for each injection. You may wish to write down the site where you have injected.
- Do not inject PROCRI[®] into an area that is tender, red, bruised, hard, or has scars or stretch marks. Recommended sites for injection are shown in Figure 11 below, including:
 - The outer area of the upper arms
 - The abdomen (except for the 2-inch area around the navel)
 - The front of the middle thighs
 - The upper outer area of the buttocks

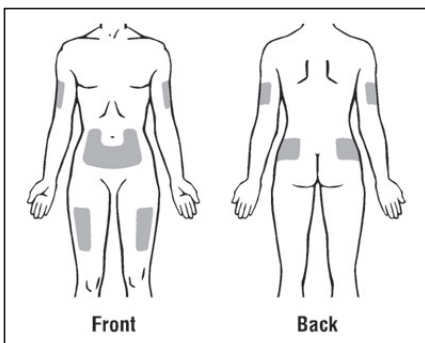


Figure 11

- Clean the skin with an alcohol wipe where the injection is to be made. Be careful not to touch the skin that has been wiped clean. See Figure 12.

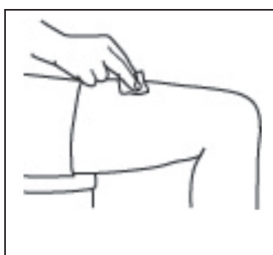


Figure 12

- Double-check that the correct amount of PROCRI[®] is in the syringe.
- Remove the prepared syringe and needle from the vial of PROCRI[®] and hold it in the hand that you will use to inject the medicine.

- Use the other hand to pinch a fold of skin at the cleaned injection site. Do not touch the cleaned area of skin. See Figure 13.

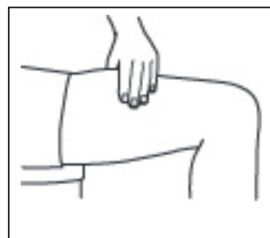


Figure 13

- Hold the syringe like you would hold a pencil. Use a quick "dart-like" motion to insert the needle either straight up and down (90-degree angle) or at a slight angle (45 degrees) into the skin. Inject the prescribed dose subcutaneously as directed by your doctor, nurse or pharmacist. See Figure 14.

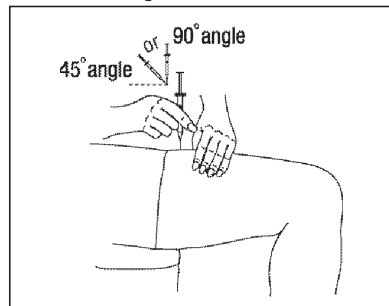


Figure 14

- Pull the needle out of the skin and press a cotton ball or gauze over the injection site and hold it there for several seconds. Do not recap the needle.
- Dispose of the used syringe and needle as described below. Do not reuse syringes and needles.

2. Intravenous Route:

- PROCRI[®] can be injected in your vein through a special access port placed by your healthcare provider. This type of PROCRI[®] injection is called an intravenous (IV) injection. This route is usually for hemodialysis patients.
- If you have a dialysis vascular access, make sure it is working by checking it as your healthcare provider has shown you. Be sure to let your healthcare provider know right away if you are having any problems, or if you have any questions.
- Wipe off the venous port of the hemodialysis tubing with an alcohol wipe. See Figure 15.

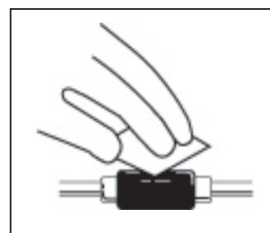


Figure 15

- Insert the needle of the syringe into the cleaned venous port and push the plunger all the way down to inject all the PROCRI. See Figure 16.

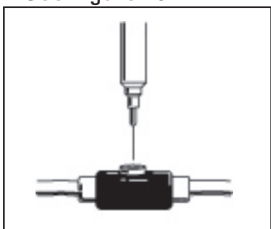


Figure 16

- Remove the syringe from the venous port. Do not recap the needle.
- Dispose of the used syringe and needle as described below.

How should I dispose of the vials, syringes, and needles?

Do not reuse the single-dose vials, syringes, or needles. Throw away the vials, syringes, and needles as instructed by your healthcare provider or by following these steps:

- Do not throw the vials, syringes, or needles in the household trash or recycle.
- Do not put the needle cover back on the needle.
- Place all used needles and syringes in a puncture-proof disposable container with a lid. Do not use glass or clear plastic containers, or any container that will be recycled or returned to a store.
- Keep the puncture-proof disposable container out of the reach of children.
- When the puncture-proof disposable container is full, tape around the cap or lid to make sure the cap or lid does not come off. Throw away the puncture-proof disposable container as instructed by your healthcare provider. There may be special state and local laws for disposing of used needles and syringes. **Do not throw the puncture-proof disposable container in the household trash. Do not recycle.**

Keep PROCRI and all medicines out of reach of children.

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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Manufactured for:

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