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:
    - o if there is not enough medicine left in the multidose vial for another dose, **or**
    - o 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.

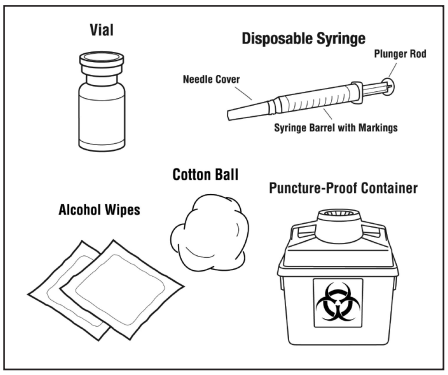

Figure 1

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

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

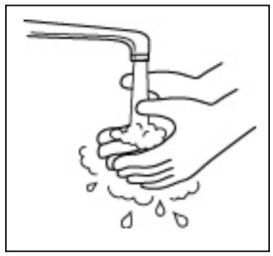

Figure 2

7. 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.

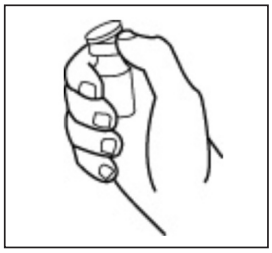

Figure 3

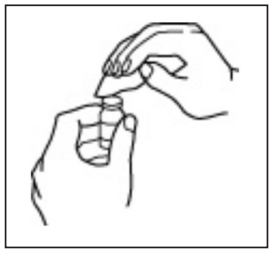

Figure 4

8. 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.
9. 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.

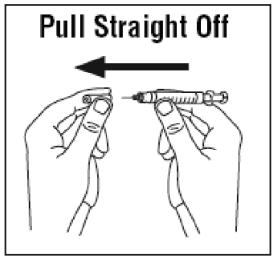

Figure 5

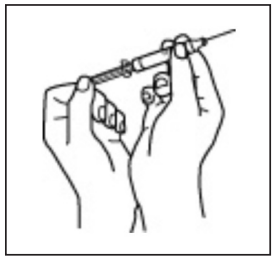

Figure 6

10. 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.
11. 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.

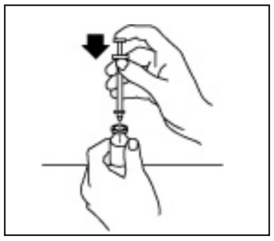

Figure 7

12. 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.

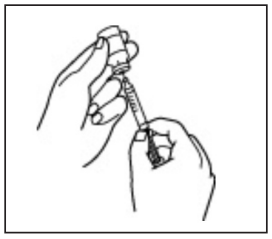

Figure 8

13. 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.

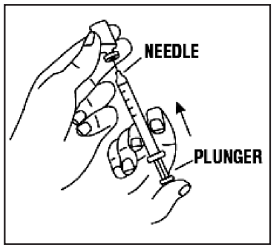

Figure 9

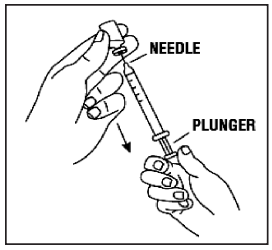

Figure 10

14. 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:

PROCRIT 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 PROCRIT. In patients on hemodialysis, the intravenous (IV) route is recommended.

1. **Subcutaneous Route:**
   - PROCRIT 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 PROCRIT 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:
     - o The outer area of the upper arms
     - o The abdomen (except for the 2-inch area around the navel)
     - o The front of the middle thighs
     - o The upper outer area of the buttocks

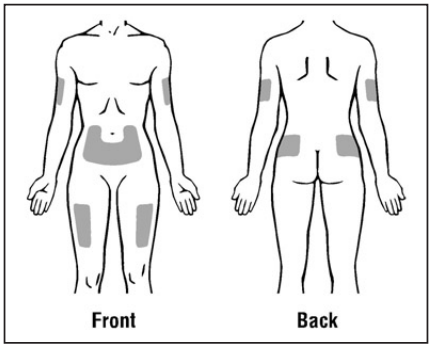

Figure 11

- 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.

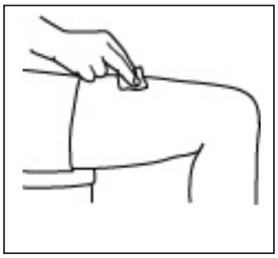

Figure 12

- Double-check that the correct amount of PROCRIT is in the syringe.
- Remove the prepared syringe and needle from the vial of PROCRIT 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.

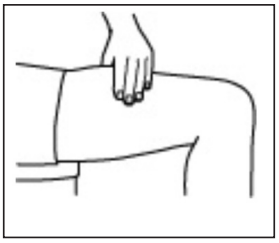

Figure 13

- 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.

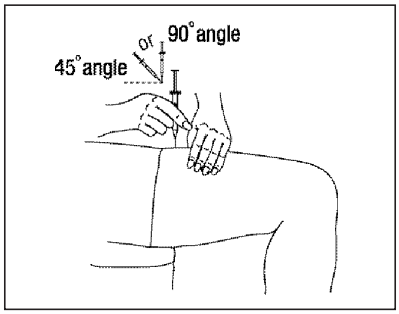

Figure 14

- 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:**
   - PROCRIT can be injected in your vein through a special access port placed by your healthcare provider. This type of PROCRIT 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.

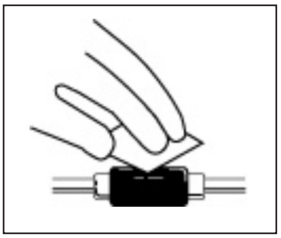

Figure 15

- Insert the needle of the syringe into the cleaned venous

port and push the plunger all the way down to inject all the PROCRIT. See Figure 16.

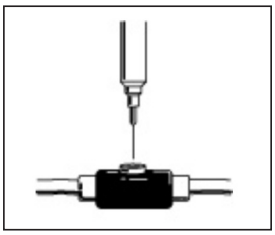

Figure 16

- 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 PROCRIT 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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