

Patient Package Insert (U.S.)—Information For Patients

CEPROTIN [Protein C Concentrate (Human)]

Pronounced: see-PRO-ten

Please read this leaflet carefully before using CEPROTIN [Protein C Concentrate (Human)]. This leaflet is based on the information provided to your doctor, and is a summary of the important information you need to know about your medicine for your severe congenital Protein C deficiency. This leaflet does not take the place of talking with your doctor and does not contain all of the information available about CEPROTIN. **This leaflet should be used only after you have received instructions from your doctor.** If you have any questions after reading this leaflet, ask your doctor or pharmacist.

1. What is CEPROTIN and what is it used for?

The name of your medicine is CEPROTIN, pronounced “see PRO ten.” CEPROTIN contains Protein C, a natural protein that is made in the liver and is present in your blood. Protein C is a part of human plasma that regulates the blood clotting (coagulation) system and prevents abnormal clot formation (thrombosis). Plasma is the liquid part of human blood.

CEPROTIN is used to treat patients with Severe Congenital Protein C Deficiency for the prevention and treatment of:

- venous thrombosis (blood clot in the vein), and
- purpura fulminans (blood spots, bruising and discoloring to skin as a result of clotting of small blood vessels in the skin).

2. How does CEPROTIN work?

CEPROTIN temporarily raises the levels of Protein C in the body. Protein C plays a major role in preventing your body from forming too many blood clots. CEPROTIN is for those patients who either don't produce enough Protein C or whose Protein C doesn't work correctly. CEPROTIN allows your body's blood clotting process to function properly.

3. Who should not use CEPROTIN?

You should not use CEPROTIN unless your doctor confirms that you have severe congenital Protein C deficiency.

You should tell your doctor about all your medical conditions.

Allergic to Mouse Protein or Heparin:

If you are known to have allergic-type reactions (rash, hives, itching, tightness of the chest, difficulty breathing, throat tightness, and low blood pressure) to mouse protein or to heparin, you should talk to your doctor before using this product. CEPROTIN contains small amounts of heparin and/or mouse protein as a result of the manufacturing process. If such a reaction occurs, you should discuss this with your doctor and your doctor will decide the right treatment.

Low-Sodium Diet/Kidney Impairment:

You should talk with your doctor before using CEPROTIN if you are on a low-sodium diet or have problems with your kidney, as the amount of sodium in the maximum daily dose of CEPROTIN exceeds 200 mg.

Pregnancy or Breast-feeding:

You should inform your doctor if you are pregnant or breast-feeding. Your doctor will decide if CEPROTIN may be used during pregnancy and/or breast-feeding.

Tell your doctor about all the medicines you are taking including prescription and nonprescription medicines, vitamins, and herbal supplements. You should also tell your doctor if you are on a special diet.

4. What is the most important information I need to know about CEPROTIN?

You could have an allergic reaction to CEPROTIN. You should be aware of the early signs of allergic reactions. These include: rash, hives, itching, tightness of the chest, difficulty breathing, throat tightness, and low blood pressure. The signs and symptoms of low blood pressure can include a weak pulse, feeling lightheaded or dizzy when you stand, and possibly shortness of breath. If you experience any of these symptoms while being treated with CEPROTIN, quickly stop the treatment and contact your doctor. If you experience a severe allergic reaction, including difficulty breathing and (near) fainting, you should quickly seek emergency treatment.

You could get an infectious disease since this drug product is made from human plasma. However, there are steps in the collection of the plasma and in the making of CEPROTIN to lessen this possibility. For example, blood and plasma donors are screened for certain viral infections. There are also steps in the processing of the plasma that can inactivate or remove viruses.

You could get an infection with a virus called Human Parvovirus B19 (B19 Virus). Fetuses are at risk to the B19 Virus. Symptoms of B19 Virus infection include fever, drowsiness, chills and runny nose followed about two weeks later by a rash and joint pain. Pregnant women should discuss this risk with their doctor.

Although, there are steps during the making of CEPROTIN to reduce the risk of getting Hepatitis A and B, your doctor may recommend that you be vaccinated against these viruses.

5. What are the possible side effects of CEPROTIN?

Like all medicines, CEPROTIN can cause side effects, although not everyone gets them.

The most serious and common side effects to CEPROTIN observed in clinical trials were allergic reactions (rash and itching) and lightheadedness.

There have also been individual reports, after the drug was marketed, of thoracic hematoma (bleeding into the chest), hypotension (very low blood pressure), fever, restlessness and increased sweating.

You could develop antibodies that can prevent CEPROTIN from working properly and therefore reduce its effect. This has not been seen in clinical studies.

If you develop any side effects, including any not listed in this leaflet, please contact your doctor.

6. How do I use CEPROTIN?

CEPROTIN is given by intravenous administration (infusion into a vein). It is given to you under the close supervision of your doctor who is experienced in replacement therapy of coagulation factors/inhibitors and where monitoring of protein C activity is possible. Your dosage will vary depending upon your condition, your age and your body weight. Your doctor may require that you have blood taken to help determine the dose of CEPROTIN that you should get. See following **Instructions for Use.**

7. How do I store CEPROTIN?

You must store CEPROTIN in powder form, without the diluent (Sterile Water for Injection) added. You should store CEPROTIN in the refrigerator at 2°C to 8°C (36°F to 46°F). Store the vial in the original carton to protect it from light. Do not freeze in order to prevent damage to the diluent vial.

Do not use CEPROTIN beyond the expiration date printed on the CEPROTIN vial.

8. What are the ingredients in CEPROTIN?

Active ingredient: human Protein C

Other ingredients: human albumin, sodium chloride and trisodium citrate dihydrate

9. What does CEPROTIN look like?

CEPROTIN is a white or cream colored powder that is mixed with the water provided in the package (Sterile Water for Injection) before injection. After mixing with the Sterile Water for Injection, the solution is colorless to slightly yellowish and clear to slightly opalescent and mostly free from visible particles.

10. What are the contents of the CEPROTIN package?

CEPROTIN comes in the following strengths:

BLUE COLOR BAR: Approximate dosage strength of 500 IU per vial.

GREEN COLOR BAR: Approximate dosage strength of 1000 IU per vial.

One package of CEPROTIN contains one vial of CEPROTIN powder, one vial of Sterile Water for Injection (diluent), one double-ended transfer needle, one filter needle, one full prescribing physician insert and one patient package insert.

11. How can I contact Baxter for more product information?

Baxter Customer Service: 1-888-CEPROTIN (237-7684)

Product website: www.ceprotin.com

Patient Package Insert (U.S.)—Instructions For Use

CEPROTIN [Protein C Concentrate (Human)]

(For intravenous use only)

IMPORTANT: Contact your doctor if you experience any problems with this procedure. These instructions are intended only as an aid for those patients who have been instructed by their doctor on the proper way to self-infuse the product. **Do not attempt to self-infuse unless you have been taught how by your doctor.**

1. Prepare a clean surface and gather all the materials you will need for the infusion. You will need to gather exam gloves (optional), alcohol swabs (or other suitable solution suggested by your doctor), a winged infusion set and a tourniquet, as these are not provided with your package of CEPROTIN.
2. Check the expiration date on the CEPROTIN vial. Do not use CEPROTIN after the expiration date.
3. Let the vial of CEPROTIN and the vial of Sterile Water for Injection, USP (diluent) warm up to room temperature.
4. Wash your hands and put on clean exam gloves (optional).
5. Remove caps from the CEPROTIN and diluent vial to expose the centers of the rubber stoppers.
6. Cleanse the stoppers with an alcohol swab (or other suitable solution suggested by your doctor) by rubbing the stoppers firmly for several seconds and allow them to dry.
7. Remove the protective covering from one end of the double-ended transfer needle and insert the exposed needle through the center of the diluent vial stopper.
8. While keeping the needle in the diluent vial, remove the protective covering from the other end of the double-ended transfer needle.
9. Invert the diluent vial over the upright CEPROTIN vial. Then, insert the free end of the needle through the CEPROTIN vial stopper at its center. The vacuum in the vial will draw in the diluent. If there is no vacuum in the CEPROTIN vial, do not use the product. Contact Baxter Customer Service.
10. Separate the two vials by removing the needle from the diluent vial stopper. Then, remove the transfer needle from the CEPROTIN vial. **Do not attempt to recap the needle and do not dispose it in ordinary household trash.** Place the needle in a hard-walled Sharps container for proper disposal.
11. Gently swirl the vial of CEPROTIN until all the powder is completely dissolved. The solution should be colorless to slightly yellowish and essentially free of visible particles. Do not use the solution if you see particles in it. CEPROTIN should be administered at room temperature within 3 hours of mixing.

12. Attach the filter needle to a disposable syringe and draw back the plunger to allow air into the syringe. Insert the filter needle into the reconstituted CEPROTIN.
13. Inject air into the vial, and then withdraw the solution into the syringe.
14. Remove and discard the filter needle from the syringe. **Do not attempt to recap the needle and do not dispose it in ordinary household trash.** Place the needle in a hard-walled Sharps container for proper disposal.
15. Attach a winged infusion set, if available, or a suitable needle (not supplied) for the injection.
16. Point the needle up and remove any air bubbles by gently tapping the syringe with your finger and slowly and carefully pushing air out of the syringe.
17. Apply a tourniquet, and prepare the injection site by wiping the skin well with an alcohol swab (or other suitable solution suggested by your doctor).
18. Insert the needle into the vein, and remove the tourniquet. Infuse CEPROTIN. CEPROTIN should be administered at a maximum injection rate of 2 milliliters (mL) per minute except for children with a body weight of <10 kg (22 pounds), where the injection rate should not exceed a rate of 0.2 mL per kilogram per minute.
19. Remove the needle from the vein and apply pressure with sterile gauze to the infusion site for several minutes. **Do not attempt to recap the needle after the infusion, and do not dispose it in ordinary household trash.** Place it with the used syringe in a hard-walled Sharps container for proper disposal.
20. Clean up any blood with a freshly prepared mixture of 1 part bleach and 9 parts water, soap and water, or any household disinfecting solution.

CEPROTIN, or its use, may be covered by one or more U.S. Patents including U.S. Patent No. 5,549,893 in addition to other patents pending.

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Important: Contact your doctor if you have any questions or experience any adverse effects. These instructions are intended as an additional aid only for those patients who have been instructed by their doctor on the proper way to self-infuse CEPROTIN. If you have not been instructed to self-infuse by your doctor, do not attempt to self-infuse.