

CEPROTIN

Protein C (human)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CEPROTIN. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CEPROTIN against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again.

What CEPROTIN is and what it is used for

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 in the treatment of purpura fulminans (blood spots, bruising and discolouring to the skin as a result of the clotting of small blood vessels in the skin) in patients born with severe protein C deficiency. Additionally, CEPROTIN may be used to treat a rare complication of a blood thinner medication (anticoagulant medication named coumarin) which may result in severe skin lesions (necrosis).

Before you are given CEPROTIN

CEPROTIN should not be given to you if:

- You have internal bleeding or have had internal bleeding over the last few months.
- You are allergic (hypersensitive) to Human Protein C or any of the other ingredients of CEPROTIN including mouse protein or heparin.
- It has passed the expiry date.

You must tell your doctor if you:

- Have any other illness.
- Are taking any prescription and non-prescription medicines, vitamins and herbal supplements.
- Are on a special diet.
- Are pregnant or breast-feeding. Your doctor will decide if CEPROTIN may be used during pregnancy and/or breast-feeding.

How CEPROTIN is given

How much is given:

Your doctor will decide how much CEPROTIN will be given to you, which depends on your need and condition.

How it is given:

CEPROTIN is given by injection into the vein. Your doctor will administer it to you. For health professionals, details are described in the Product Information.

If you are given too much:

In case you received more CEPROTIN than recommended, please inform your doctor as soon as possible.

If you stop using CEPROTIN:

Do not stop using this medicine without consulting your doctor.

While you are using CEPROTIN

Discuss with your doctor the progress you have experienced after the treatment, especially during the first few days. As CEPROTIN is given in a hospital, your healthcare professional will keep records of your progress and any unexpected reactions that may occur.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CEPROTIN. This medicine helps most people with severe protein C deficiency, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes, they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Some patients may have sudden signs of allergy. Your doctor is aware of this potential adverse effect, in particular as CEPROTIN contains a protein as an active ingredient. Hypersensitivity or allergic reactions (which may include hives, generalized rash, tightness of the chest, wheezing and low blood pressure) have been observed in some patients. Burning and stinging at injection sites, fever, chills, flushing, headaches, tiredness, nausea, vomiting, dizziness, excessive sweating and restlessness have also been reported. In clinical trials with patients born with severe protein C deficiency, mild allergic reactions were reported.

In exceptional cases, symptoms of a serious allergic reaction may occur, known as an "anaphylactic shock". If you experience a rash, swelling of the face, lips or mouth, or difficulty in breathing, tell your healthcare professional immediately.

If you are born with severe protein C deficiency, your body may develop antibodies that may decrease the effectiveness of this medicine.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Product description

What CEPROTIN looks like

It is presented as a white to cream coloured powder in a single dose glass vial accompanied by sterile water for injection in glass vial to be used for reconstitution. After reconstitution, the solution is colourless to slightly yellowish and should be clear to slightly opalescent. It should be essentially free from visible particles.

What CEPROTIN contains

CEPROTIN comes in two strengths: 500 IU and 1000 IU. The active component of CEPROTIN is protein C, which is isolated from the blood of healthy donors. It also contains human albumin, which acts as a stabilizer.

CEPROTIN contains 500 IU or 1000 IU of Human Protein C. It also contains:

- Human albumin
- Sodium chloride
- Sodium citrate
- Sterile water for injection

How to store CEPROTIN

CEPROTIN is a protein preparation; therefore it should be stored between 2°C and 8°C in a refrigerator.

Name and Address of the Sponsor

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This leaflet was prepared in May 2015.

AUST R 104537 (500 IU)

AUST R 104538 (1000 IU)

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