# CEPROTIN®

*Protein C*

**Consumer Medicine Information**

## What is in this leaflet?

This leaflet answers some common questions about CEPROTIN. It does not contain all 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 using CEPROTIN against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**
You may need to read it again.

## What CEPROTIN 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).

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**
Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

## Before you are given CEPROTIN

### *About blood products*

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed from the blood/plasma donor to the person receiving the medicine.

These processes include careful selection of the people who donate blood and plasma to make sure that those who might be carrying infections are excluded. In addition, each donation and pools of donations are tested for indicators of virus or virus infection(s).

Manufacturers of these medicines also include steps in the processing of blood or plasma that inactivate or remove viruses. Despite the stringent measures, which have been put in place during the manufacturing processes, the risk of contamination by viral and other unknown agents cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and for the non-enveloped hepatitis A virus (HAV).

The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals whose immune system is depressed or who have some types of anaemia (e.g.: haemolytic anaemia).

Your doctor may recommend that you consider vaccination against hepatitis A and B if you regularly/ repeatedly receive human plasma-derived Protein C products.

### *CEPROTIN should not be given to you if:*

You are allergic (hypersensitive) to:

- human Protein C or
- any of the other ingredients of CEPROTIN listed at the end of this leaflet, including
  - mouse protein or
  - Heparin, except for control of life-threatening thrombotic complications.

Some of the symptoms of an allergic reaction may include:

- tightness of chest
- wheezing or difficulty breathing
- low blood pressure
- shock
- rash, itching or hives on the skin.

If such symptoms occur during the administration of CEPROTIN, injection should be stopped, and your doctor will decide on the most appropriate treatment.

It is strongly recommended that every time you receive a dose of CEPROTIN the name and batch number of the product are recorded to maintain a record of the batches used.

**Do not give this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**
If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should have this medicine, talk to your doctor.**

### *Before you start to take CEPROTIN*

**Tell your doctor if you have or have had any of the following medical conditions:**

- hypersensitivity/allergic reaction to mouse protein and/or to heparin
- Heparin induced Thrombocytopenia
- internal bleeding or have had internal bleeding over the last few months
- on a controlled sodium diet. CEPROTIN 500 IU contains 22.5 mg sodium per vial, equivalent to 1.1% of the WHO recommended maximum daily intake of 2 g sodium for an adult. CEPROTIN 1000 IU contains 44.9 mg sodium per vial, equivalent to 2.2% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
  As the quantity of sodium in the maximum daily dose may exceed 200 mg, this should be taken into consideration by patients on a controlled sodium diet.

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**
Your doctor will decide if CEPROTIN may be used during pregnancy and/or breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

No interactions with other medicinal products are currently known.

If you change to treatment with oral anticoagulants (e.g. warfarin), treatment with CEPROTIN must continue until the blood level of the oral anticoagulation is adequate and stable.

You may need different amounts of your medicines, or you may need to take different medicines.

## How CEPROTIN is given

**Follow all directions given to you by your doctor or pharmacist carefully.**
They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

### *How much is given*

The dose, administration frequency and duration of treatment depend on the severity of the protein C deficiency as well as on your clinical condition and on your plasma level of protein C. They should be adjusted accordingly based on clinical effectiveness and laboratory assessment.

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 a vein. Your doctor will administer it to you. For health professionals, details are described in the Product Information.

### *How long to use it*

**Do not stop using the medicine without consulting your doctor.**

### *If you are given too much (overdose)*

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

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much CEPROTIN. Do this even if there are no signs of discomfort or poisoning.**

## While you are using CEPROTIN

### *Things you must do*

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.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

### *Things to be careful of*

This medicine is not expected to affect your ability to drive a car or operate machinery.

If you experience dizziness, light-headedness, tiredness or drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using 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.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

As with any product administered by infusion into a vein, allergic reactions including severe and potentially life-threatening reactions (anaphylaxis) are possible but have not been seen with CEPROTIN.

Your doctor is aware of this potential adverse effect, as CEPROTIN contains a protein as an active ingredient.

**Nevertheless, tell your doctor or pharmacist if you notice any of the following and they worry you:**

- hypersensitivity or allergic reactions (which may include hives, generalized rash, tightness of the chest, wheezing and low blood pressure)
- burning and stinging at injection sites,
- fever, chills, flushing, headaches, tiredness, nausea, vomiting, dizziness and excessive sweating.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.**

- in clinical trials with patients born with severe protein C deficiency, mild allergic reactions were reported
- the following side effects were very rarely observed during clinical studies: fever, wheals (urticaria), itching (pruritus), rash and dizziness
- if you are born with severe protein C deficiency, your body may develop antibodies that may decrease the effectiveness of this medicine
- in the post marketing experience, there have been reports of restlessness; bleeding, excessive sweating, fever, arrhythmia and thrombosis were reported.

These side effects are very rare.

**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.

### *Storage*

**CEPROTIN is a protein preparation; therefore, it should be stored between 2°C and 8°C in a refrigerator. Do not freeze. Protect from light.**

Keep it where children cannot reach it.

### *Disposal*

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## Product description

### *What CEPROTIN looks like*

It is presented as a white to cream coloured powder in a single dose glass vial accompanied by water for injections 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.

### *Ingredients*

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 the following ingredients:

- Human albumin
- Sodium chloride
- Sodium citrate dihydrate
- Water for injections

### *Manufacturer*

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This leaflet was prepared in July 2024.

AUST R 104537 (500 IU)

AUST R 104538 (1000 IU)