

Ceprothin®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CEPROTIN?

CEPROTIN is used in the treatment of purpura fulminans (blood spots, bruising and discolouring to the skin because 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).

For more information, see Section [1. Why am I using CEPROTIN?](#) in the full CMI.

2. What should I know before I use CEPROTIN?

Do not use if you have ever had an allergic reaction to CEPROTIN or any of the ingredients listed at the end of the CMI including mouse protein or heparin, except for control of life-threatening thrombotic complications.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use CEPROTIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CEPROTIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use CEPROTIN?

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. CEPROTIN is given by injection into a vein. Your doctor will administer it to you.

More instructions can be found in Section [4. How do I use CEPROTIN?](#) in the full CMI.

5. What should I know while using CEPROTIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are using CEPROTIN.</p> <ul style="list-style-type: none"> • Discuss with your doctor the progress you have experienced after the treatment.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine without consulting your doctor.
Driving or using machines	<ul style="list-style-type: none"> • This medicine is not expected to affect your ability to drive a car or operate machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Be careful when drinking alcohol while taking this medicine.
Looking after your medicine	<ul style="list-style-type: none"> • Store between 2°C and 8°C. Refrigerate; do not freeze. • Protect from light.

For more information, see Section 5. What should I know while using CEPROTIN? in the full CMI.

6. Are there any side effects?

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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cepro[®]

Active ingredient(s): *[Protein C, human]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cepro[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CEPROTIN.**

Where to find information in this leaflet:

- [1. Why am I using CEPROTIN?](#)
- [2. What should I know before I use CEPROTIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CEPROTIN?](#)
5. What should I know while using CEPROTIN?
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using CEPROTIN?

CEPROTIN contains the active ingredient Protein C, a natural protein that is made in the liver and is present in your blood. Protein C is 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 because of the clotting of small blood vessels in the skin) in patients born with severe protein C deficiency
- 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.

2. What should I know before I use CEPROTIN?

Warnings

Do not use CEPROTIN if you are allergic to human Protein C, or any of the ingredients listed at the end of this leaflet including mouse protein or heparin.

However, in the case of life-threatening thrombotic complications, your doctor may still decide to continue treatment with CEPROTIN.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include the following:

- 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.

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 indications 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.

Check with your doctor if you have:

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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.

CEPROTIN contains sodium.

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 (main component of cooking/table salt) **in the maximum daily dose may exceed 200 mg, this should be taken into consideration by patients on a controlled sodium diet.**

3. What if I am taking other medicines?

No interactions with other medicinal products are currently known. Nevertheless, tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

If you change to treatment with oral anticoagulants (e.g. warfarin), treatment with CEPROTIN must continue until stable anticoagulation is achieved as assessed by your doctor.

Some medicines may interfere with CEPROTIN and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CEPROTIN.

4. How do I use CEPROTIN?

CEPROTIN is given by injection into a vein after reconstitution of the powder for injection with the provided solvent (Water for Injections).

Your doctor will administer it to you.

For healthcare professionals, details are described in the Product Information.

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.

How much to use

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.

5. What should I know while using CEPROTIN?

Things you should do

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.

- 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 you should not do

Do not stop using this medicine without consulting your doctor.

Driving or using machines

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 that could be dangerous.

Looking after your medicine

- CEPROTIN is a protein preparation; therefore, it should be stored between 2°C and 8°C in a refrigerator.
- Do not freeze.
- Store in the outer carton to protect from light.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>In clinical trials:</p> <ul style="list-style-type: none">• with patients born with severe protein C deficiency, mild allergic reactions were reported• rarely observed adverse effects: fever, wheals (urticaria), itching (pruritus), rash and dizziness <p>If you were born with severe protein C deficiency: your body may develop antibodies that may decrease the</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>effectiveness of this medicine</p> <p>Post marketing experience:</p> <ul style="list-style-type: none"> ● restlessness, ● bleeding, ● excessive sweating, ● fever, ● arrhythmia ● thrombosis 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Anaphylaxis <p>As with any product administered by infusion into a vein, acute allergic reactions including severe and potentially life-threatening reactions are possible.</p> <p>Your doctor is aware of this potential adverse effect, as, CEPROTIN contains a protein as an active ingredient.</p>	<p>Administration should be performed within reach of life-supporting facilities.</p> <p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Hypersensitivity or allergic reactions - which may include hives, generalized rash, tightness of chest, wheezing and low blood pressure ● Burning and stinging at injection sites ● Fever, chills, flushing, headaches, tiredness, nausea, vomiting, dizziness and excessive sweating. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

Once you have consulted with a healthcare professional regarding any side effects that you have experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CEPROTIN contains

CEPROTIN comes in two strengths: 500 IU (AUST R 104537) and 1000 IU (AUST R 104538). 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.

Active ingredient	Human protein C
Other ingredients	Human albumin Sodium chloride Sodium citrate dihydrate Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

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 a 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.

Who distributes CEPROTIN

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney, NSW 2000

Australia

Telephone: 1800 012 612

This leaflet was prepared in August 2024.

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