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Ceprotin (*human protein C*)

An overview of Ceprotin and why it is authorised in the EU

What is Ceprotin and what is it used for?

Ceprotin is a medicine used in patients with severe congenital protein C deficiency, a condition that increases the risk of blood clots. It is used to treat and prevent:

- purpura fulminans (extensive clotting of blood within the blood vessels, which causes the death of the tissues just beneath the skin, often leading to organ failure and amputations);
- coumarin-induced skin necrosis (a complication of medicines used to prevent blood clotting such as warfarin, which causes skin death);
- venous thromboembolism (problems due to the formation of blood clots in the veins).

Ceprotin contains the active substance human protein C.

How is Ceprotin used?

Ceprotin treatment should only be started by a doctor who has experience in this type of therapy and in a setting where it is possible to measure protein C activity. Ceprotin is given by injection into a vein. It should only be given in a facility with life-supporting facilities as allergic reactions are possible.

The medicine can only be obtained with a prescription. For more information about using Ceprotin, see the package leaflet or contact your doctor or pharmacist.

How does Ceprotin work?

Ceprotin contains human protein C, extracted and purified from human plasma (the liquid part of the blood). In the body, protein C controls the generation of thrombin, one of the substances (factors) involved in blood clotting. Protein C slows down the production of thrombin, and therefore slows down further clotting. An injection of Ceprotin gives an immediate but temporary increase in levels of protein C. Replacement of protein C in protein C-deficient patients should control or prevent clotting problems in these patients.

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What benefits of Ceprotin have been shown in studies?

An analysis of 79 patients, 22 of whom had severe forms of congenital protein C deficiency, looked at how well Ceprotin treatment could bring the patients' levels of protein C and other substances involved in clotting to normal levels and improve their skin lesions. In patients with severe congenital protein C deficiency, Ceprotin was effective at treating all 16 cases of purpura fulminans and all six episodes of coumarin-induced skin necrosis.

In addition, a study in 18 patients with severe congenital protein C deficiency showed that Ceprotin was effective at treating all of the 24 episodes of purpura fulminans, coumarin-induced skin necrosis and venous thromboembolism that occurred in a total of 11 patients. When used for short or long-term prevention, no purpura fulminans, coumarin-induced skin necrosis or venous thromboembolism occurred.

What are the risks associated with Ceprotin?

Hypersensitivity (allergic reactions), including severe reactions, can occur with Ceprotin.

Ceprotin must not be used in people who may be hypersensitive (allergic) to human protein C, mouse protein or to heparin, except in life-threatening complications.

For the full list of all side effects of Ceprotin, see the package leaflet.

Why is Ceprotin authorised in the EU?

Studies have shown that Ceprotin can treat and prevent purpura fulminans, coumarin-induced skin necrosis and venous thromboembolism, which are major complications in patients with severe congenital protein C deficiency. Safety data have also shown that the side effects of the medicine are rare and manageable.

The Agency therefore concluded that Ceprotin's benefits are greater than its risks for patients with severe congenital protein C deficiency and recommended and recommended that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Ceprotin?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ceprotin have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ceprotin are continuously monitored. Suspected side effects reported with Ceprotin are carefully evaluated and any necessary action taken to protect patients.

Other information about Ceprotin

Ceprotin was granted a marketing authorisation valid throughout the EU on 16 July 2001.Further information on Ceprotin can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ceprotin

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