10 November 2022
EMA/858603/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ceprotin

human protein C

On 10 November 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Ceprotin. The marketing authorisation holder for this medicinal product is Takeda Manufacturing Austria AG.

The CHMP adopted an extension to the existing indication to include the prophylaxis of purpura fulminans and coumarin-induced skin necrosis as well as the prophylaxis and treatment of venous thrombotic events.

For information, the full indications for Ceprotin will therefore be as follows:[2]

> CEPROTIN is indicated for **prophylaxis and treatment** of purpura fulminans, coumarin-induced skin necrosis **and venous thrombotic events** in patients with severe congenital protein C deficiency.
> ~~Furthermore, CEPROTIN is indicated for short-term prophylaxis in patients with severe congenital protein C deficiency if one or more of the following conditions are met:~~
> ~~• surgery or invasive therapy is imminent~~
> ~~• while initiating coumarin therapy~~
> ~~• when coumarin therapy alone is not sufficient~~
> ~~• when coumarin therapy is not feasible.~~

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold, removed text as strikethrough

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