



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2024  
EMA/423647/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Esperoct

turoctocog alfa pegol

On 19 September 2024, 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 Esperoct. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

Treatment and prophylaxis of bleeding in patients ~~12 years and above~~ with haemophilia A (congenital factor VIII deficiency).

**Esperoct can be used for all age groups.**

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 made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough

