24 July 2025
EMADOC-1700519818-2288040
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Alhemo

concizumab

On 24 July 2025 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 Alhemo. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted an extension to the existing indication of routine prophylaxis of bleeding to include treatment of patients aged 12 years and older with severe haemophilia A without factor VIII inhibitors and with moderate/severe haemophilia B without factor IX inhibitors. The full indications of Alhemo will therefore be as follows:[2]

> Alhemo is indicated for routine prophylaxis of bleeding in patients 12 years of age or more with:
>
> - haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors.
> - **severe haemophilia A (congenital factor VIII deficiency, FVIII <1%) without FVIII inhibitors.**
> - haemophilia B (congenital factor IX deficiency) with FIX inhibitors.
> - **moderate/severe haemophilia B (congenital factor IX deficiency, FIX ≤2%) without FIX inhibitors.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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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