17 September 2026
EMADOC-1829012207-71075
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Frehemgo
denecimig

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Frehemgo, intended for routine prophylaxis of bleeding episodes in patients with haemophilia A.

The applicant for this medicinal product is Novo Nordisk A/S.

Frehemgo will be available as 1.6 mg, 4 mg, 9 mg, 20 mg and 46 mg solution for injection in pre-filled pen. The active substance of Frehemgo is denecimig, an antihaemorrhagic (ATC code: B02BX13). Denecimig is a fully human modified immunoglobulin G4 antibody that acts as a mimetic of activated factor VIII (FVIII). It bridges activated coagulation factor IX (FIXa) and coagulation factor X (FX) on the surface of activated platelets, thereby promoting the generation of activated FXa.

The benefit of Frehemgo is its ability to reduce bleeding events in children, adolescents and adults with haemophilia A. The most common side effects with Frehemgo are injection site reactions, prothrombin fragment 1.2 increased and fibrin D dimer increased.

The full indication is:

> FREHEMGO is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency):
>
> - with FVIII inhibitors
> - without FVIII inhibitors who have,
>   - severe disease (FVIII < 1%)
>   - moderate disease (FVIII ≥ 1% and ≤ 5%) requiring prophylaxis treatment.
>
> This medicinal product can be used in all age groups.

Treatment must be initiated under the supervision of a physician experienced in the management of haemophilia and/or bleeding disorders.

[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.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.