17 October 2024
EMA/470073/2024 Corr. 1[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Alhemo

concizumab

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Alhemo, intended for the prevention of bleeding in patients with haemophilia A and FVIII inhibitors or haemophilia B and FIX inhibitors.

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

Alhemo will be available as solution for injection in pre-filled pen containing 15 mg/1.5 ml, 60 mg/1.5 ml, 150 mg/1.5 ml or 300 mg/3 ml of concizumab. The active substance of Alhemo is concizumab, an antihaemorrhagic, other systemic haemostatics (ATC code: B02BX10). Concizumab is a humanised monoclonal antibody that targets tissue factor pathway inhibitor (TFPI), an inhibitor of factor Xa (FXa). By binding to TFPI, concizumab prevents inhibition of FXa. The resulting increase in FXa activity prolongs the initiation phase of coagulation and allows sufficient thrombin generation for effective haemostasis. Concizumab acts independently of FVIII and FIX.

When given as prophylaxis, the benefit of Alhemo is the prevention of bleeding in patients with haemophilia A and FVIII inhibitors or haemophilia B and FIX inhibitors. This benefit was observed at 24 to 32 weeks of treatment in a superiority study that compared the effects of concizumab prophylaxis to no prophylaxis. The most common side effects with Alhemo are hypersensitivity and reactions at the site of injection.

The full indication is:

> Alhemo is indicated for routine prophylaxis of bleeding in patients with:
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> - haemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and of 12 years of age or more.

[1] This SmOP was updated on 30 October 2024 to reflect that the benefit of Alhemo in the prevention of bleeding in patients with haemophilia A and FVIII inhibitors or haemophilia B and FIX inhibitors was observed at 24 to 32 weeks of treatment
[2] 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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- haemophilia B (congenital factor IX deficiency) with FIX inhibitors and of 12 years of age or more.

Alhemo should be prescribed by doctors experienced in the treatment of haemophilia and/or bleeding disorders. Treatment should be initiated when the patient does not have active bleeding.

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