Healthcare Professional Guide

Important safety information on the risk of thromboembolic events.

Alhemo® ▼(concizumab)

This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie.

Adverse reactions/events can also be reported to the Novo Nordisk Medical Department at complaintireland@novonordisk.com or Tel: 01 8629700.

This guide is part of the educational materials developed by Novo Nordisk and is a mandatory condition of the Marketing Authorisation to minimise the risk of thromboembolic events associated with the use of Alhemo®.

Risk minimisation materials for Alhemo® have been approved by the Health Products Regulatory Authority (HPRA), Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2.

For more information on potential risks associated with the use of Alhemo® and measures to minimise risk, please see the Summary of Product Characteristics (SmPC), which is available on www.medicines.ie or on www.ema.europa.eu.

Authorised indication

Alhemo® (concizumab) is an anti-tissue factor pathway inhibitor (anti-TFPI) antibody and is indicated for routine prophylaxis of bleeding in patients (≥ 12 years of age) 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

IMPORTANT SAFETY INFORMATION

Please read this information carefully before prescribing the product

Risk of thromboembolic events associated with Alhemo®

- Cases of non-fatal arterial and venous thromboembolic events have been reported in the concizumab clinical trials. These cases occurred in patients with multiple risk factors including high or frequent doses of breakthrough bleed treatment.
- Patients treated with concizumab should be informed of and monitored for the occurrence of signs and symptoms of thromboembolic events.
- In case of suspicion of thromboembolic events, concizumab should be discontinued, and further investigations and appropriate medical treatment should be initiated (see Summary of Product Characteristics (SmPC) section 4.2 for detailed information and guidance on posology).
- There should be careful periodic consideration whether the potential benefit of concizumab treatment outweighs the potential risk in patients considered at high risk of thromboembolic events.
- Caution should be exercised when the patient is at high risk of developing thromboembolic events.
- In conditions in which tissue factor is overexpressed (e.g. advanced atherosclerotic disease, crush injury, cancer, or septicaemia), there may also be a risk of thromboembolic events or disseminated intravascular coagulation (DIC).

Dose and schedule of bypassing agents to manage breakthrough bleeds

- No dose adjustment of Alhemo® should be done in case of breakthrough bleeds.
- Physicians should discuss with the patient and/or caregiver about the dose and schedule of bypassing agents, if required while receiving Alhemo® prophylaxis. Refer to Section 4.2 of the SmPC for detailed information and guidance on posology and method of administration.
- Treatment with bypassing agents (e.g., rFVIIa or aPCC) can be used for breakthrough bleeds, and the dose and duration will depend on the location and severity of the bleed.
- **For mild and moderate bleeds** that require additional treatment with bypassing agents (e.g., rFVIIa or aPCC), the lowest approved dose and the dose interval as in the approved label is recommended. Furthermore, for aPCC a maximum dose of 100 U/kg body weight within 24 hours is recommended.
- **For severe bleeds** it is recommended to follow the dosing scheme provided in the approved label for the specific product based on clinical judgement.

Patient alert card and patient/carer guide

All patients initiating treatment with Alhemo® must receive a patient alert card and patient/carer guide from the treating physician or other healthcare professional. The patient must always carry the alert card. These educational materials have been created to inform patients and carers about an important risk of thromboembolism and how to manage this including the importance of seeking medical help immediately in case the patient experiences signs or symptoms. Ensure patients read and understand these materials.

The treating physician should recommend the patient to always carry the alert card and to show it to any healthcare professional treating the patient. This includes any physician, pharmacist, nurse or dentist the patient is consulting and not only the haemophilia specialist prescribing this medicine.

Additional patient alert cards and patient guides can be requested by contacting Novo Nordisk Limited, Ireland on 01 8629700 or infoireland@novonordisk.com.

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