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## **Alhemo access in UAE: the MOHAP and EDE named-patient pathway**

How patients in the United Arab Emirates with hemophilia A or B obtain Alhemo (concizumab-mtci) once-daily subcutaneous prophylaxis through the federal unregistered-medicine import permit.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

*Alhemo is FDA-approved for hemophilia A or B prophylaxis in patients 12 years and older; it is not registered in the UAE as of this review date. UAE patients access it through the federal named-patient framework with cold-chain logistics.*

### **Quick orientation for UAE patients**

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Alhemo, the brand name for concizumab-mtci, is a humanized IgG4 monoclonal antibody manufactured by Novo Nordisk that targets tissue factor pathway inhibitor (TFPI) to restore thrombin generation in patients whose coagulation cascade is broken by an absence of factor VIII or factor IX activity. The U.S. Food and Drug Administration first approved Alhemo on 20 December 2024 for adult and pediatric patients aged 12 and older with hemophilia A or B with inhibitors, and later expanded the label to hemophilia A or B without inhibitors. It is dosed once daily by subcutaneous injection. Alhemo is not registered in the UAE, so a Dubai or Abu Dhabi pharmacy cannot supply it through standard channels. The federal named-patient framework, administered through MOHAP and (from 29 December 2025) the Emirates Drug Establishment, is the legal route. Reserve Meds coordinates US specialty-pharmacy sourcing, cold-chain export, and UAE-side import permits so the family does not lose continuity. Reserved for you.

### **Why patients in the UAE need Alhemo via the named-patient pathway**

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Hemophilia A and B with inhibitors is a rare-within-rare patient population. UAE hematology centers see these patients but the case volumes do not yet justify Novo Nordisk pursuing a UAE marketing authorisation, which is the structural reason Alhemo is not on the federal register here. The drug is approved by reference authorities (FDA, EMA December 2024, UK MHRA October 2025, Health Canada, PMDA Japan, Australia TGA, Sweden), which satisfies the reference-authority requirement of the MOHAP and EDE framework.

Patients commonly reach for Alhemo over older bypass agents (recombinant factor VIIa, activated prothrombin complex concentrate) because those agents treat acute bleeds rather than prevent them. For hemophilia A with inhibitors, emicizumab (Hemlibra) is the principal competing prophylaxis. For hemophilia B with inhibitors, emicizumab is not indicated and concizumab is one of the first prophylactic options. The once-daily subcutaneous regimen is also a meaningful quality-of-life shift from infusion-based bypass therapy, particularly for adolescents and adults managing daily life around bleed prevention. The clinical choice between concizumab

and emicizumab sits with the treating hematologist; the procurement is what the named-patient framework solves.

## **The MOHAP and EDE named-patient pathway for Alhemo**

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The unregistered-medicine import permit, administered through the EDE portal at [ede.gov.ae](http://ede.gov.ae) from 29 December 2025 under Federal Decree-Law No. 38 of 2024, is the federal pathway. For Alhemo specifically, the cell-level clinical-justification angle is the prior-line failure or contraindication for emicizumab (in hemophilia A with inhibitors) or the absence of a competing prophylactic agent (in hemophilia B with inhibitors), plus the case for once-daily subcutaneous prophylaxis over on-demand bypass therapy.

A complete application typically includes:

- A clinical justification letter from the treating adult or pediatric hematologist. The letter documents the hemophilia diagnosis (A or B), the inhibitor status (titer history measured in Bethesda units), the bleeding history (annualized bleeding rate over the prior 12 months, joint involvement, hospitalization episodes), prior bypass-agent or prophylactic-agent experience, the reason for selecting concizumab specifically, and the prescribed regimen.
- The treating physician's emirate-specific medical license verification (MOHAP for the Northern Emirates, DHA for Dubai, DOH for Abu Dhabi, or Sharjah Health Authority for Sharjah).
- An anonymized patient identifier with age, weight, and inhibitor titer attached.
- Full product detail: brand name Alhemo, generic name concizumab-mtci, manufacturer Novo Nordisk, the pen strengths requested (60 mg in 1.5 mL, 150 mg in 1.5 mL, 300 mg in 3 mL), quantity calculated against the weight-based maintenance dose, and intended treatment duration (chronic, no defined finite course).
- The destination dispensing facility name, pharmaceutical establishment license number, and pharmacy in charge.
- A chain-of-custody plan for a 2 to 8 degrees Celsius cold-chain biologic. Validated insulated packaging with temperature loggers, customs documentation flagging refrigerated content, and end-to-end logging from the US specialty pharmacy through international courier to the UAE dispensing pharmacy. Pens must not be frozen and excursions outside 2 to 8 degrees Celsius compromise stability.

Approval timelines for routine hemophilia inhibitor cases generally fall within the 5 to 15 business days window typical of the framework. Complex first-of-molecule reviews can extend to 4 to 6 weeks. Cold-chain handling adds 2 to 3 days to physical transit relative to ambient products, which is built into the case calendar.

## **Where Alhemo gets dispensed in the UAE**

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The institutional set that handles Alhemo most naturally overlaps with established hematology service lines and centers with 2 to 8 degrees Celsius cold-chain pharmacy infrastructure. Sheikh Khalifa Medical City in Abu Dhabi, on the SEHA network and managed by the Cleveland Clinic, runs hematology services and an in-house import pharmacy with cold-chain capability. Cleveland Clinic Abu Dhabi handles adult hematology with cold-chain pharmacy. American Hospital Dubai, a Mayo Clinic Care Network member, has hematology and hemophilia care experience. Tawam

Hospital in Al Ain handles adult and pediatric hematology and oncology. Mediclinic City Hospital in Dubai Healthcare City and King's College Hospital London Dubai handle adult hematology. NMC Healthcare flagship sites have hematology service lines.

For families based in the Northern Emirates, the standard pattern is to route the case through a Dubai or Abu Dhabi hematology center where the treating hematologist holds joint privileges. A specialty importer in Dubai or Abu Dhabi can also file the EDE permit and deliver the cold-chain shipment under chain-of-custody to the prescribing hospital's outpatient pharmacy.

### **Real cost picture for Alhemo in the UAE**

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Per Drugs.com and specialty pricing references, the US list price for Alhemo pens is approximately USD 10,088 for the 60 mg pen, USD 25,209 for the 150 mg pen, and