Alhemo access in Egypt: the EDA personal-importation pathway

How patients in Cairo, Alexandria, and across Egypt legally obtain Alhemo (concizumab-mtci) from US source supply for once-daily subcutaneous bleed prophylaxis in hemophilia A or B with inhibitors when the medicine is not yet registered locally.

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

Quick orientation

Alhemo (concizumab-mtci) is a humanized IgG4 monoclonal antibody from Novo Nordisk that targets tissue factor pathway inhibitor (TFPI) to restore factor Xa and thrombin generation in patients with hemophilia A or B with or without inhibitors. The US Food and Drug Administration first approved Alhemo in December 2024 for routine prophylaxis to prevent or reduce bleeding episodes in adult and pediatric patients 12 years and older with hemophilia A or B with inhibitors, and later expanded the label to include patients without inhibitors. The dosing is once-daily subcutaneous via prefilled pen. In Egypt, Alhemo is not yet registered as a locally marketed product through the Egyptian Drug Authority (EDA), and patients managed at the country's specialty hematology centres who need TFPI-pathway prophylaxis look for a structured legal route to obtain it. That route is the EDA personal-importation framework, filed through a licensed dispensing institution by the treating hematologist.

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Why Egyptian patients need Alhemo via the named-patient pathway

Egypt has a substantial hemophilia population concentrated at university hospital hematology services, and the Egyptian Hemophilia Association supports the wider patient community across the country. Patients with hemophilia A or B who have developed inhibitors (neutralising antibodies to factor VIII or factor IX replacement) live with the daily reality that conventional factor replacement no longer works for them, and the available bypass strategies (recombinant factor VIIa, activated prothrombin complex concentrate) are on-demand acute-bleed agents rather than continuous prophylaxis. Emicizumab is the principal alternative for hemophilia A with inhibitors but is not indicated for hemophilia B. Alhemo is one of the first prophylactic options that covers both hemophilia A and hemophilia B with inhibitors in a single product, with a once-daily subcutaneous regimen that is meaningfully easier on quality of life than infusion-based bypass therapy.

The structural reason patients reach for the EDA personal-importation pathway is direct: Alhemo is not on the EDA registration list. Even where a treating hematologist at Kasr Al Ainy, Ain Shams, or a private sector centre identifies Alhemo as the appropriate next step, the patient cannot fill the prescription at a registered Egyptian pharmacy because the product has no local marketing authorisation. The inhibitor population is rare-within-rare, the disease-modifying logic for daily TFPI-pathway prophylaxis is strong, and the named-patient route is the only legal path to the molecule in Egypt today.

The EDA personal-importation pathway for Alhemo

The Egyptian Drug Authority was created by Law No. 151 of 2019, with executive regulations issued by Prime Minister Decision No. 777 of 2020. EDA permits the importation of unregistered medicines for a specific named patient where no equivalent registered product is available locally, or where the available alternative cannot meet the patient's clinical need. The personal-importation framework is the dominant administrative term; Special Access and Compassionate Use appear in EDA correspondence as variations on the same underlying workflow.

A complete Alhemo application typically includes:

- A clinical justification letter from the treating hematologist, on hospital letterhead, with original signature and stamp, stating the hemophilia diagnosis (A or B), the documented inhibitor status with the most recent Bethesda titer or, for the non-inhibitor expansion population, the rationale for switching from current therapy, the prior prophylactic and bypass regimens with response and tolerability data, and the specific clinical reason TFPI-pathway prophylaxis with concizumab is the appropriate next step
- The treating physician's Egyptian Medical Syndicate membership number and Ministry of Health licence reference
- A recent prescription specifying brand name (Alhemo), generic name (concizumab-mtci), strength (60 mg/1.5 mL, 150 mg/1.5 mL, or 300 mg/3 mL prefilled pen), and quantity required calculated against the patient's weight-based loading and maintenance dose
- Patient identifier: copy of the national ID card or passport
- Full product details: manufacturer (Novo Nordisk A/S, Bagsvaerd, Denmark, US operations Plainsboro NJ), country of origin, FDA approval reference, shelf life, 2 to 8 degree Celsius cold-chain storage class
- Destination dispensing facility licence (the hospital pharmacy or licensed importer pharmacy that will physically receive, store under refrigeration, and dispense the pens)
- Chain-of-custody plan covering validated 2 to 8 degree Celsius cold-chain packaging with continuous temperature loggers, air freight through Cairo International Airport, customs clearance, and last-mile transfer to the dispensing facility under documented temperature logging at every handoff

For Alhemo, the clinical justification letter benefits from explicit documentation of the inhibitor titer (or the rationale for the non-inhibitor population), the patient's bleeding history with annualised bleeding rate where available, the dosing plan (1 mg/kg loading dose Day 1 followed by 0.2 mg/kg once daily from Day 2, with the 4-week plasma concentration check that drives titration to 0.15, 0.20, or 0.25 mg/kg per the FDA label), and an explicit thrombosis risk assessment given the boxed regulatory caution around TFPI-pathway prophylaxis after the explorer7 and explorer8 trial signal. Routine EDA personal-import authorisations for well-documented hematology cases are typically processed within a 3 to 6 week window, with complex first-import biologic-class cases extending to 8 to 14 weeks.

Where Alhemo gets dispensed in Egypt

Alhemo is a refrigerated biologic in a single-patient prefilled pen. The Egyptian institutions that fit this profile with established import pharmacy infrastructure and routine experience with refrigerated biologics include Cairo University Hospitals (Kasr Al Ainy), the oldest and largest

academic hospital network in Egypt and the Middle East, with a Drug Information Center and dedicated hematology services; Ain Shams University Hospitals, the second major academic hospital network in Cairo with strong hematology and pediatric programs; and on the private side Dar Al Fouad Hospital in 6th of October City (Alameda Healthcare Group, JCI-accredited since 2005, with over 250 bone marrow transplants and active hematology services), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group facilities.

For pediatric and adolescent patients (the label starts at age 12), Children's Cancer Hospital Egypt 57357 routinely handles refrigerated specialty biologic imports, though hemophilia care typically sits at the university hospital pediatric hematology services rather than at the oncology-focused 57357. Smaller regional hospitals typically route through one of the Cairo centres or through a licensed specialty importer in Cairo. The Egyptian Hemophilia Association does not file EDA personal-import applications, but the treating hematology service it works with does.

Real cost picture for Alhemo in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. The Egyptian pound has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026 per Trading Economics historical data, and a controlled-depreciation outlook through end of year per IMF Article IV consultation forecasts. Quoting in USD insulates the family from intra-case EGP drift between quote and shipment.

Per Drugs.com and specialty pricing references, Alhemo US list pricing is approximately USD 10,088 per 60 mg pen, USD 25,209 per 150 mg pen, and USD 50,411 per 300 mg pen. Annual cost depends meaningfully on patient weight because dosing is weight-based. For a typical adult patient at 70 kg on the 0.2 mg/kg maintenance dose, daily consumption is approximately 14 mg, or roughly 420 mg per month before loading-dose effects. At US list pricing, annualised cost lands well above USD 500,000 per patient per year, consistent with rare-disease prophylaxis pricing benchmarks for bypass and substitution biologics. Exact annual spend varies with body weight, titration outcome, and any negotiated payer pricing.

International cold-chain logistics from US source to Cairo International Airport typically run USD 600 to 1,500 per shipment, reflecting the validated 2 to 8 degree Celsius packaging, continuous temperature loggers, and disruption tolerance that a daily-dose biologic requires (daily dosing leaves no buffer for prolonged customs delays). EDA permit administrative fees on the Egyptian side vary by dispensing facility and importer. Reserve Meds itemises the US-side drug procurement, the international logistics, and the concierge coordination fee separately on every firm quote.

Local payer reality is cash-dominant. UHIA does not currently cover most specialty imports. Private insurers operating in Egypt (Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance) assess named-patient claims case by case. We do not promise coverage. Many Egyptian families coordinate USD funds from relatives in the Gulf, the UK, or North America for sustained rare-disease prophylaxis cases.

Typical timeline for Alhemo in Egypt

For a routine Egypt Alhemo case with a complete documentation package, EDA personal-import authorisation typically lands in 3 to 6 weeks. The cold-chain biologic class adds 2 to 3 days to the operational timeline compared with ambient-product shipments because of validated 2 to 8 degree Celsius packaging and continuous temperature monitoring across multi-leg international transit. First-time imports of a daily-dose subcutaneous biologic can add 1 to 2 weeks for

institutional pharmacy onboarding at the dispensing facility, particularly around the cold-storage allocation and the pen-training workflow. Once the first cycle is in place, subsequent monthly shipments follow the same chain on a planned cadence to avoid the daily-dose continuity risk that delayed customs would create.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA application. For Alhemo the strongest letters consistently include the hemophilia diagnosis (A or B) with factor activity documented, the inhibitor status with the most recent Bethesda titer (or, for the non-inhibitor population, the rationale for switching from current therapy), the bleeding history with annualised bleeding rate where available, the prior prophylactic and bypass regimens with response data, the proposed dosing plan (1 mg/kg loading dose Day 1, 0.2 mg/kg once daily from Day 2, with the protocol-specified plasma concentration check at approximately 4 weeks and titration logic to 0.15, 0.20, or 0.25 mg/kg per the FDA label), an explicit thrombosis-risk assessment and bypass-agent stacking plan if breakthrough bleeds occur, the monitoring plan covering plasma concentration, thromboembolic signs and symptoms, and anti-drug antibody assessment if response declines, and the treating physician's EMS membership and MoH licence references.

The treating physician retains the clinical decision and the pharmacovigilance reporting obligation through the Egyptian Pharmacovigilance Center (EPVC). Reserve Meds supplies the documentation template and the chain-of-custody packet from the US side; we do not write the clinical letter, do not advise on the concizumab-versus-emicizumab choice, and do not direct dosing.

Common questions about Alhemo in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover Alhemo?

Each insurer assesses named-patient imports case by case. Some plans reimburse a percentage when the drug treats a covered indication even if the specific product is not on a local formulary; many require pre-authorisation. We do not promise coverage. We supply the documentation set that allows your insurer to assess, and the claim sits with the family or the dispensing hospital. Cash-pay is the default posture.

Why concizumab versus emicizumab?

Emicizumab (Hemlibra) is approved only for hemophilia A and is dosed weekly to monthly subcutaneously. Concizumab is once-daily subcutaneous and covers both hemophilia A and hemophilia B with inhibitors in a single product. For hemophilia B with inhibitors specifically, emicizumab is not indicated and concizumab is one of the first prophylactic options. The treater chooses. Reserve Meds does not recommend one over the other.

What is the thrombosis risk we should be aware of?

In the explorer7 and explorer8 trials, three serious thromboembolic events were reported, including a renal infarction, which prompted a clinical-hold pause, a dose reduction from 0.25 mg/kg to 0.20 mg/kg maintenance, and explicit risk-mitigation guidance on concurrent bypass-agent dosing. Patients with risk factors for thrombosis require careful assessment by the treating hematologist. Breakthrough-bleed management uses the lowest approved dose of any concurrent procoagulant per the label.

Is Alhemo a controlled substance?

No. Alhemo is a biologic and is not on any DEA schedule. Reserve Meds coordinates Alhemo imports under the standard EDA personal-importation framework for unregistered biologics.

Can we self-administer Alhemo at home?

The dispensing facility must hold a valid Egyptian pharmacy or hospital licence to receive the pen under cold chain. After training, patients or caregivers self-administer the daily subcutaneous injection at home, with injection sites rotating between abdomen, thigh, and upper arm per label. The dispensing chain ends at the licensed pharmacy; the daily injection happens at home.

What if our family lives between Cairo and the Gulf?

Reserve Meds runs patient-side coordination in Arabic where requested and family-side coordination in English in parallel, with a single named coordinator running the case end to end. We support family correspondence across the UAE, Saudi Arabia, the UK, North America, and elsewhere in the Egyptian diaspora.

Where Reserve Meds fits in Alhemo cases

Reserve Meds is a US-based concierge coordinator. We do not replace your hematologist, do not replace EDA, do not replace your dispensing pharmacy, and do not act as an importer of record in Egypt. What we do is orchestrate the US-side specialty channel sourcing on a valid US prescription, prepare the documentation kit your physician needs for the EDA personal-import filing, coordinate the international cold-chain logistics to Cairo International Airport with validated 2 to 8 degree Celsius packaging and continuous temperature monitoring, and run a single named concierge throughout the case. Alhemo has no prior Reserve Meds case experience as of this review, so the operating posture is standard NPP coordination with particular attention to cold-chain integrity (a daily-dose biologic has zero tolerance for prolonged customs delays), the 4-week plasma concentration titration step in the FDA label, and continuity of supply across the chronic-therapy refill cycles that define long-term prophylaxis.

Next step

If you or a family member have hemophilia A or B with inhibitors (or hemophilia A or B without inhibitors under the expanded label) and your treating hematologist is considering Alhemo, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your physician and an indicative USD cost range based on the current weight and dosing plan.

Reserved for you.

This guide is informational, not medical or legal advice. The EDA personal-importation framework requires a licensed Egyptian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.