

# Hemlibra access in the Kingdom of Saudi Arabia

How families in the Kingdom pursue Hemlibra (emicizumab-kxwh), Roche's bispecific factor IXa- and factor X-directed humanized monoclonal antibody, through the SFDA Personal Importation Program.

*Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the Saudi Arabia country research module with the Hemlibra drug module to describe the path families actually walk.*

## Quick orientation

Hemlibra (emicizumab-kxwh) is Roche's bispecific antibody for hemophilia A prophylaxis. It bridges factor IXa and factor X to restore the function missing factor VIII would otherwise provide, and it works in patients with or without factor VIII inhibitors. It received FDA approval in 2017 for inhibitor patients and in 2018 for the broader hemophilia A population. For Saudi Arabia hemophilia A families weighing emicizumab, this page describes the SFDA Personal Importation Program pathway.

## Why this drug is hard to source in Saudi Arabia

Hemophilia A is the most common severe inherited bleeding disorder, and KSA has an established hemophilia treatment center network anchored at KFSH&RC and the major academic centers. Hemlibra has had SFDA registration progress, and many patients can access it through the conventional supply chain. The access gap shows up when local stock is interrupted, when a pediatric patient is started on subcutaneous prophylaxis at a center where the dose form they need is not on the shelf, or when the family is in a region of the Kingdom where the supply is less consistent. The PIP route lets the treating hematologist bridge that gap for a named patient.

## The SFDA Patient Import Permit (PIP) pathway applied to Hemlibra

The Saudi Food and Drug Authority's Personal Importation Program is the federal pathway that allows an SCFHS-licensed physician to import a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (typically the US

FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Hemlibra (emicizumab-kxwh) holds FDA approval since 2017 for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in hemophilia A patients with or without factor VIII inhibitors (all ages), which places it squarely within the framework's scope.

The application is filed through the dispensing institution's import pharmacy (or, where the institution does not hold internal import-pharmacy capability, through an SFDA-licensed specialty importer in Riyadh or Jeddah). The standard package contains the clinical justification letter from the treating physician, the SCFHS license verification, the anonymized patient identifier, the full product details for Hemlibra including subcutaneous injection (multiple vial strengths: 30 mg, 60 mg, 105 mg, 150 mg, 300 mg), weekly, every two weeks, or every four weeks dosing, with cold-chain handling at 2 to 8 degrees Celsius documented in the file, the destination dispensing facility license, and the chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy. The SFDA portal at [sfda.gov.sa](http://sfda.gov.sa) handles regulatory transactions, and named-patient activity increasingly routes through the agency's Ghad digital platform.

## **Where Hemlibra gets dispensed in the Kingdom**

The major Saudi institutions that handle named-patient imports as established workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) with operations in Riyadh, Jeddah, and Madinah; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network; King Saud University Medical City and the academic medical centers; King Khalid University Hospital; Dr. Sulaiman Al Habib Medical Group (HMG) across multiple Riyadh, Jeddah, and Eastern Province facilities; the Saudi German Hospital network; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. Smaller hospitals typically route their named-patient cases through one of these centers or through an SFDA-licensed specialty importer. For a Hemlibra case, the dispensing facility is selected on the basis of where the treating physician practices and where the patient receives ongoing care; Reserve Meds does not select the dispensing facility on the family's behalf.

## **Real costs in SAR and USD**

The US wholesale acquisition cost for Hemlibra varies by maintenance dose schedule. For a typical adult patient on every-two-week dosing (3 mg/kg every two weeks), monthly drug cost is approximately USD 30,000 to USD 40,000, translating to roughly SAR 112,500 to SAR 150,000. Pediatric patients receiving lower doses are correspondingly lower. Cold-chain logistics for a refrigerated biologic add approximately SAR 3,000 to SAR 5,600 per shipment. The treatment is chronic and ongoing payer engagement is central. Hemophilia care in KSA

often has structured insurer coverage given the well-established hemophilia treatment center model.

Reserve Meds quotes an indicative range based on the initial intake and then a transparent firm quote with each line item shown separately. The Reserve Meds concierge fee is published on a tiered schedule and is shown as a separate line. Nothing is bundled. Nothing is hidden.

## **Timing, what to expect**

The SFDA Personal Importation Program processes routine cases (recognized reference-authority drug, well-documented indication, established institution) in approximately 10 to 20 business days. Complex cases (novel mechanism, off-label use within the FDA label scope, ultra-rare patient population, first-time importer) can extend to 6 to 8 weeks. SFDA does not publish guaranteed turnaround times, so case-by-case planning is the norm. In parallel with the SFDA review, Reserve Meds aligns the US-side sourcing, the packaging and cold-chain validation, and the shipment plan, so the drug is ready to move on the day approval comes through. The patient experience runs through ten well-defined steps from initial physician decision through reorder coordination; the full ten-step sequence is documented in the Saudi Arabia country module and in our patient-facing operations brief.

## **What your physician needs to provide**

The treating hematologist's clinical justification letter typically documents the confirmed hemophilia A diagnosis (factor VIII activity below 1 percent for severe), the factor VIII inhibitor status (Bethesda titer), the bleeding history including any joint bleeds and target joints, prior factor VIII concentrate prophylaxis history and breakthrough bleeding, the rationale for emicizumab over factor VIII prophylaxis, and the proposed loading and maintenance schedule (weekly, every two weeks, or every four weeks). The SCFHS registration in hematology or pediatric hematology accompanies the letter.

The dispensing facility's SFDA-licensed pharmacy completes the submission and accepts the chain-of-custody documentation. The institutional license is what authorizes the dispensing pharmacy to receive the imported drug, so the physician's individual SCFHS license is necessary but not sufficient on its own. Post-import pharmacovigilance commitment to report adverse events through the SFDA National Pharmacovigilance Center is part of the application and runs through the full course of therapy, not just the initial dose.

## **Vision 2030 and the specialty-access environment**

Saudi Vision 2030's Health Sector Transformation Program (HSTP) is the operating frame for healthcare reform in the Kingdom. HSTP is restructuring the Ministry of Health from a provider-and-regulator into a regulator and strategist, with clinical delivery devolving into regional Health Clusters and Centers of Excellence. The program names tertiary cancer care, rare-disease care, organ transplantation, genomics, and digital health as priority verticals, all of which are heavy users of specialty drugs not registered locally. The practical effect on the PIP framework is twofold. HSTP is expanding the universe of specialty drugs that get formal SFDA registration, which closes some access gaps. At the same time, HSTP is increasing diagnostic capacity in rare disease and oncology genomics, which surfaces new patients who need drugs that are FDA-approved but not yet registered in the Kingdom. The named-patient framework remains essential for the foreseeable future. Saudization (the Nitaqat workforce-nationalization program) does not change the PIP framework, but confirming the prescriber's SCFHS license status before filing is good practice in any case where the treating physician is in a renewal window.

## **Pharmacovigilance and cold-chain considerations**

Hemlibra carries a boxed warning for thrombotic microangiopathy and thromboembolic events when used with activated prothrombin complex concentrate (aPCC) at cumulative doses of 100 units/kg/24 hours or more for 24 hours or more. The SFDA pharmacovigilance commitment includes the documented co-treatment guidance for breakthrough bleeding (recombinant factor VIIa as preferred bypassing agent, aPCC only at minimum effective dose) and any thrombotic event reporting. Cold-chain at 2 to 8 degrees Celsius is required.

Reserve Meds' physician documentation kit includes the SFDA adverse-event reporting reference so the treating physician has the framework on hand from day one. Reserve Meds does not file adverse-event reports; that responsibility sits with the SCFHS-licensed treating physician. The dispensing facility carries the chain-of-custody and storage obligations through the dispensing event, and off-label transfer of the imported supply to another patient is not permitted under the PIP framework.

## **Common questions about Hemlibra in the Kingdom**

**Will Bupa Arabia, Tawuniya, or MedGulf cover this?** Each insurer handles named-patient imports case by case under the Council of Cooperative Health Insurance (CCHI) framework. Some plans reimburse fully when the medicine appears on the insurer's formulary even where the local hospital pharmacy does not stock it. Others reimburse a percentage. Many require pre-authorization with the clinical justification letter attached. Reserve Meds supplies the documentation that lets the insurer assess the case; the claim is yours or your

hospital's to file. Cash-pay is the default operating posture for cross-border access, with reimbursement sought after delivery where your plan permits.

**Will my Ministry of Health-employed physician's letter be sufficient if SFDA flags the case?** Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, KSUMC, and other public-sector institutions have full signing authority on PIP applications under their SCFHS license. The clinical justification letter is the cornerstone of the package. Private-sector physicians at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

**Can I receive the drug at home, or do I need a hospital?** The dispensing facility must be a locally licensed pharmacy. For oral medicines, a hospital outpatient pharmacy or specialized SFDA-licensed import pharmacy dispenses to the patient. For infusion or injection products, the medicine ships to the infusion center where you will receive it. Direct-to-home delivery without a licensed dispensing facility in the chain is not the operating model.

**What about pediatric patients?** The PIP framework applies to pediatric patients the same way it applies to adults. The clinical justification letter typically includes weight-based dosing, pediatric-specific monitoring, and where relevant the involvement of the pediatric specialty center. KFSH&RC, KAMC, and the major HMG facilities have established pediatric specialty programs that handle named-patient imports routinely.

**How does Saudization (Nitaqat) affect my case?** Saudization is the workforce-nationalization program that shapes hospital staffing composition. It does not change the PIP framework. It can occasionally affect timing if a non-Saudi treating physician's license is in renewal at the moment the PIP file is being prepared. Confirming the prescriber's SCFHS license status before filing is good practice.

**Is Hemlibra a controlled substance?** No. Hemlibra is not a US DEA scheduled substance. The Saudi narcotics-section approvals do not apply. The chain-of-custody documentation, the dispensing facility's pharmaceutical establishment license, and the SFDA pharmacovigilance commitment do apply.

## **Where Reserve Meds fits in Hemlibra cases**

Reserve Meds is a US-based concierge coordinator. We do not replace your treating physician, the SFDA, the dispensing pharmacy, or the institutional import-pharmacy team. For a Hemlibra case in the Kingdom, our work is to orchestrate the US-side sourcing, prepare the regulatory documentation kit your physician needs, coordinate international logistics with cold-chain validation where required, and assign a single named coordinator who stays with the case through reorders. The clinical decisions remain with the treating physician. The regulatory authority remains SFDA. The dispensing remains with the

licensed Saudi pharmacy. Reserve Meds is the connective tissue between the US supply side and those three Saudi pillars. Reserved for you.

## Next step

If a treating physician in the Kingdom is weighing Hemlibra for a patient, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

*Reserved for you.*

## Related

- Hemlibra clinical resource
- Hemlibra in the United Arab Emirates
- Hemlibra in Qatar
- Hemlibra in Kuwait
- Kingdom of Saudi Arabia country page

## Sources

1. FDA approval, Hemlibra (emicizumab-kxwh), Roche (Genentech in the US), initial FDA approval 2017.
2. Saudi Food and Drug Authority (SFDA), Personal Importation Program framework, <https://www.sfda.gov.sa/en>, and the Ghad digital regulatory platform at <https://ghad.sfda.gov.sa/>.
3. Saudi Vision 2030, Health Sector Transformation Program, <https://www.vision2030.gov.sa/en/explore/programs/health-sector-transformation-program>.
4. Saudi Commission for Health Specialties (SCFHS), <https://scfhs.org.sa/en>, for treating-physician licensing and the institutional pharmacy framework.

**Review and oversight.** Content on this page is reviewed by the Reserve Meds clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology >

Last medically reviewed: 2026-05-12.