Fabhalta access in Saudi Arabia: the SFDA Personal Importation Program

How patients in the Kingdom of Saudi Arabia access Fabhalta (iptacopan) for PNH, IgA nephropathy, and C3 glomerulopathy, with the REMS vaccination prerequisite.

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

1. Quick orientation

Fabhalta is the brand name for iptacopan, an oral twice-daily small-molecule selective inhibitor of factor B in the alternative complement pathway. By acting proximally to the C3 convertase, iptacopan controls both intravascular and extravascular hemolysis in paroxysmal nocturnal hemoglobinuria (PNH) and reduces complement-mediated tissue injury in complement-driven kidney diseases. The US Food and Drug Administration approved Fabhalta for PNH in adults on December 5, 2023 (first oral monotherapy approved for the indication), for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression on August 8, 2024 under accelerated approval, and for C3 glomerulopathy (C3G) in adults on March 20, 2025 (first treatment approved for this rare kidney disease). Fabhalta is developed and commercialised by Novartis. In the Kingdom of Saudi Arabia, the Saudi Food and Drug Authority (SFDA) has no local marketing authorisation for Fabhalta as of this page's review date. Saudi patients whose treating hematologist or nephrologist has confirmed eligibility reach Fabhalta through the SFDA Personal Importation Program (PIP), with completion of the REMS-mandated vaccination protocol as the defining prerequisite. Reserved for you.

2. Why Saudi Arabia patients need Fabhalta via the named-patient pathway

Three patterns of access gap apply across the Kingdom: a drug is registered with SFDA but not stocked at the treating hospital on the day the patient needs it; a drug is registered with SFDA for one indication but the physician is prescribing it for a different FDA-approved indication that has not been added to the local label; or a drug is FDA-approved but the manufacturer has never sought SFDA registration. Fabhalta sits in the third pattern. There is no local marketing authorisation for Fabhalta in the Kingdom or in any GCC market as of this page's review date, and there is no local-agent supply route for Saudi patients with PNH, IgAN at risk of rapid disease progression, or C3G.

Four converging factors drive Fabhalta to the named-patient route. First, the international registration gap: outside the US, EU, and UK (and Japan for C3G), the drug has no local marketing authorisation in major MENA and Gulf markets including the Kingdom. Second, the underlying diseases are ultra-rare or under-served. PNH affects roughly 1 to 2 per million population. C3 glomerulopathy is rarer still. IgA nephropathy is more common but has historically had limited disease-modifying options, and Fabhalta is the first complement-targeted therapy approved. National payers in non-approved jurisdictions have limited incentive to expedite local registration for such small patient pools. Third, the patient populations are highly motivated. Patients facing chronic transfusion dependence (PNH) or progressive kidney decline (IgAN, C3G) are well-informed via international advocacy networks and seek the first oral monotherapy across borders. Fourth, the modality is logistically simple. Oral capsules, room temperature, no cold chain. The complexity is regulatory (REMS vaccination, country NPP filing) rather than physical.

Saudi Vision 2030's investment in tertiary nephrology, hematology, and rare-disease care surfaces newly diagnosed patients with PNH (often via flow cytometry detecting GPI-anchor-deficient blood cells), biopsy-proven IgA nephropathy at risk of rapid progression, and biopsy-proven C3 glomerulopathy. These are exactly the populations the named-patient framework is designed to serve.

3. The SFDA Personal Importation Program for Fabhalta

The SFDA Personal Importation Program allows a Kingdom-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable for the patient. The framework explicitly contemplates hematology and rare-disease therapies. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector, with activity increasingly routed through the Ghad digital platform alongside the agency's English portal at sfda.gov.sa.

A complete PIP application for Fabhalta includes the clinical justification letter from the treating hematologist (PNH) or nephrologist (IgAN, C3G); the treating physician's licensing verification through the Saudi Commission for Health Specialties (SCFHS) in the relevant specialty; the patient identifier in the format SFDA requires for the named-patient case file; full product details (Fabhalta, iptacopan, Novartis, 200 mg hard gelatin capsules, 60-capsule bottle providing 30-day supply at the approved twice-daily regimen, requested quantity including refill plan); the destination dispensing facility license; and a chain-of-custody plan for ambient shipment from the US point of release through international transit to the receiving Saudi pharmacy.

The clinical-justification angle for Fabhalta turns on indication-specific diagnostic confirmation plus REMS vaccination documentation. For PNH, the treating hematologist documents the flow cytometry result confirming GPI-anchor-deficient red and white blood cell populations, clinical hemolysis parameters (LDH, hemoglobin, transfusion history), and treatment history (eculizumab or ravulizumab exposure and response, where applicable, with reference to the APPLY-PNH switch data and APPOINT-PNH treatment-naive data). For IgA nephropathy, the treating nephrologist documents the biopsy-proven IgAN diagnosis, proteinuria measurement, blood pressure control on optimised RAS inhibition, and rate of progression markers consistent with the APPLAUSE-IgAN population. For C3 glomerulopathy, the treating nephrologist documents the biopsy-proven C3G diagnosis (immunofluorescence and electron microscopy findings) and the rationale for using the first and only FDA-approved C3G-specific therapy. In every case, the letter explicitly confirms that the patient has completed (or has a documented plan to complete) the REMS-mandated vaccinations against meningococcal (ACWY and B), pneumococcal, and Haemophilus influenzae type b at least 2 weeks before initiation. Approval timelines for routine SFDA cases run 10 to 21 business days; complex first-import REMS-restricted cases can extend to 6 to 10 weeks.

4. Where Fabhalta gets dispensed in Saudi Arabia

Fabhalta is a room-temperature oral hard gelatin capsule supplied in 200 mg strength, 60 capsules per bottle (30-day supply), with no refrigeration, reconstitution, or infusion infrastructure required. The dispensing requirement is therefore an SFDA-licensed hospital outpatient pharmacy or specialty import pharmacy aligned with a hematology service (PNH) or nephrology service (IgAN, C3G) capable of REMS-style monitoring (clinical surveillance for serious infection, liver function tests, lipid monitoring).

Kingdom institutions with adult hematology and nephrology services that handle named-patient imports of REMS-restricted complement inhibitors as routine workflow include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with tertiary hematology, organ transplant, nephrology, and rare-disease capability and an experienced in-house import pharmacy; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network with strong tertiary hematology and nephrology programs; King Saud University Medical City (KSUMC); Dr. Sulaiman Al Habib Medical Group (HMG), the largest private hospital network in the Kingdom with multiple Riyadh, Jeddah, and Eastern Province facilities and routine PIP activity; Saudi German Hospital; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. The REMS infection-warning sign protocols and the indication-specific monitoring stacks (CBC and LDH for PNH, proteinuria and eGFR for IgAN, complement profiling and proteinuria for C3G) are operationalised at the institutional level rather than at SFDA.

5. Real cost picture for Fabhalta in Saudi Arabia

The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, which makes the dollar-denominated US wholesale acquisition cost the principal driver of the case economics. Three line items frame the cost.

First, drug cost. The US wholesale acquisition cost for Fabhalta at the approved 200 mg twice-daily regimen is approximately USD 566,500 per year, with the WAC per 30-day fill reported at approximately USD 46,562 as of March 2025 (roughly SAR 174,600 per 30-day bottle and SAR 2,124,400 per annual course). This is the manufacturer-stated US list price before payer negotiation, not patient out-of-pocket cost in the US. The Novartis copay support program (up to USD 20,000 annually for commercially insured US patients) and US patient assistance programs are domestic only and do not extend to international named-patient cases. Pricing references include the Vermont 30-day Reporting filing for Novartis Fabhalta 200 mg x 60, HCAI WAC reporting, and the ICER PNH evidence report.

Second, international logistics. Fabhalta is room-temperature stable with permitted excursions to 15 to 30 degrees Celsius, which is the most permissive class of handling. International logistics for an ambient shipment to the Kingdom typically runs SAR 1,500 to SAR 3,750 (approximately USD 400 to USD 1,000) and does not require cold-chain validation, temperature monitoring, or insulated packaging. Customs delays do not threaten product integrity within the documented stability window.

Third, regulatory and coordination. SFDA documentation handling fees, REMS-channel verification of the upstream US specialty pharmacy partner (Biologics by McKesson or Onco360), and Reserve Meds' concierge fee are itemised separately. On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case by case, with most requiring pre-authorisation given the annual cost. The Council of Cooperative Health Insurance (CCHI) governs plan structure. Cash-pay is the default operating posture for an indefinite-duration chronic therapy of this cost, with annual budgeting from the first case. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately.

6. Typical timeline for Fabhalta in Saudi Arabia

The SFDA timeline for routine PIP cases runs 10 to 21 business days. Fabhalta is an ambient oral capsule, so cold-chain transit time does not apply, but the REMS vaccination prerequisite is the dominant timing variable. End-to-end, a typical Fabhalta case in the Kingdom runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; an indication-specific diagnostic confirmation step (flow cytometry for PNH, kidney biopsy review for IgAN and C3G) which is typically already in the patient file; a vaccination window of at least 2 weeks before initiation for meningococcal (ACWY and B), pneumococcal, and Haemophilus influenzae type b vaccinations per the most current ACIP recommendations (some patients require 4 to 6 weeks if the full vaccination series is incomplete); 3 to 7 days for the treating physician and dispensing pharmacy or specialty importer to assemble the PIP application including REMS vaccination documentation; 10 to 21 business days for SFDA review (longer for first-time complement-inhibitor imports into the institution, where 6 to 10 weeks is plausible); 3 to 5 days for US sourcing through Biologics by McKesson or Onco360 under REMS-certified channels and DSCSA-compliant chain-of-custody, with qualified ambient shipment; 1 to 3 days for Saudi customs clearance under the PIP permit; and final receipt and release at the dispensing pharmacy. Repeat-shipment cadence is planned from the first case because Fabhalta is chronic and indefinite across all three approved indications.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP application. The treating Kingdom hematologist or nephrologist documents the patient's indication (PNH in adults, primary IgA nephropathy in adults at risk of rapid disease progression, or C3 glomerulopathy in adults), with ICD-10 coding and indication-specific diagnostic confirmation in the file (flow cytometry for PNH, kidney biopsy report for IgAN and C3G with proteinuria and eGFR documentation as appropriate); states the planned dosing regimen (200 mg by mouth twice daily, doses approximately 12 hours apart, capsules swallowed whole and not opened, crushed, or chewed, with or without food, no loading dose, treatment chronic and indefinite); confirms drug-interaction review (avoid strong CYP2C8 inhibitors including gemfibrozil and strong

CYP3A4 inducers); explains why a locally registered alternative is not suitable (no oral complement inhibitor is locally registered in the Kingdom; intravenous anti-C5 antibodies eculizumab and ravulizumab and the subcutaneous C3 inhibitor pegcetacoplan are different modalities and routes); and describes the indication-specific monitoring plan.

The REMS-mandated vaccination protocol is a hard prerequisite. The letter explicitly confirms that the patient has completed, or has a documented plan to complete, vaccinations against meningococcal (ACWY and B), pneumococcal, and Haemophilus influenzae type b at least 2 weeks before initiation, per the most current ACIP recommendations for patients receiving complement inhibitors. The label permits initiation before completion of vaccinations only when the risk of delay outweighs the infection risk, in which case appropriate antibiotic prophylaxis is documented. The monitoring stack across indications includes clinical surveillance for signs of serious infection throughout therapy with prompt evaluation of any fever or systemic symptoms; baseline and periodic liver function tests (ALT, AST, total bilirubin); lipid monitoring per clinician judgment; patient education on infection-warning-sign recognition with a patient safety card; and indication-specific clinical parameters (CBC, LDH, hemoglobin, transfusion history for PNH; urinary protein, eGFR, blood pressure for IgAN and C3G).

The letter is co-filed with the physician's SCFHS license verification, the institutional pharmacy license, the requested bottle count and refill plan, and the chain-of-custody plan for the ambient shipment to the dispensing site. Post-import, the treating physician and dispensing pharmacy commit to adverse-event reporting through the SFDA National Pharmacovigilance Center for the full course of therapy.

8. Common questions about Fabhalta in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Fabhalta? Each plan handles named-patient imports case by case. Some reimburse fully when the medicine appears on the insurer's formulary; others reimburse a percentage; most require pre-authorisation with the clinical justification letter attached given the annual cost. Reserve Meds supplies the documentation that lets the insurer assess; the claim is yours or your hospital's to file. We do not promise coverage from any insurer.

Will my hematologist's or nephrologist's letter be sufficient? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. Private-sector hematologists and nephrologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Is the vaccination protocol really required before starting? Yes. Vaccination against meningococcal (ACWY and B), pneumococcal, and Haemophilus influenzae type b is a REMS requirement and a label-mandated prerequisite, at least 2 weeks before initiation per the most current ACIP recommendations for patients receiving complement inhibitors. The label permits initiation before completion of vaccinations only when the risk of delay outweighs the infection risk, in which case appropriate antibiotic prophylaxis is considered. Reserve Meds requires documentation of the treating physician's vaccination plan before coordinating supply.

What is the safety profile I should know about? Fabhalta carries a boxed warning for serious infections caused by encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae type b). Serious infections occurred in 6.7 percent of iptacopan-treated patients versus 2.1 percent on placebo in APPLAUSE-IgAN. Other common adverse reactions across APPLY-PNH, APPOINT-PNH, and APPLAUSE-IgAN include headache, nasopharyngitis, diarrhoea, abdominal pain, bacterial infection, nausea, and elevated lipids. Liver function abnormalities have been observed and warrant baseline and periodic monitoring.

Is there a competitor or alternative? For PNH, alternatives include the intravenous anti-C5 antibodies eculizumab (Soliris) and ravulizumab (Ultomiris) and the subcutaneous C3 inhibitor pegcetacoplan (Empaveli). Fabhalta is the first oral monotherapy. For IgAN, alternatives include RAS inhibition (ACE/ARB), SGLT2 inhibitors, sparsentan, and budesonide (Tarpeyo). For C3G, no other FDA-approved disease-specific therapy exists; supportive care had been the standard. The treating hematologist or nephrologist makes the selection. Reserve Meds does not endorse one regimen over another.

What is the typical course duration? Fabhalta is intended for chronic use across all three indications. There is no finite course. Treatment continues for as long as the prescribing physician judges that benefit outweighs risk. The cost of

indefinite therapy is a primary factor in international access conversations and is built into annual planning from the first case.

9. Where Reserve Meds fits in Fabhalta cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating hematologist or nephrologist, SFDA, the dispensing hospital pharmacy or specialty importer, the REMS-certified upstream US specialty pharmacy (Biologics by McKesson or Onco360), your vaccination team, or your insurer. What we do for a Fabhalta case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the 200 mg twice-daily regimen, the indication-specific diagnostic requirements, the FABHALTA REMS vaccination protocol, and the boxed-warning monitoring stack; align US-side sourcing through REMS-certified specialty pharmacy channels under DSCSA-compliant chain-of-custody; coordinate ambient shipment with a qualified specialty 3PL; and provide a single named Patient Concierge Coordinator across repeat shipments and chronic refill cadence. Because Fabhalta is REMS-restricted and chronic-indefinite, the case complexity sits in the REMS vaccination documentation and chronic-cadence planning rather than in physical logistics. No prior Reserve Meds case experience predates this page; standard NPP coordination applies, with REMS vaccination evidence as the defining gating step.

10. Next step

If your Kingdom hematologist or nephrologist has confirmed an FDA-approved Fabhalta indication and the REMS vaccination plan is in place or completed, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's 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 ›
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