Fabhalta access in Egypt: the EDA personal-import named-patient pathway

How patients in Egypt access Fabhalta (iptacopan) for paroxysmal nocturnal hemoglobinuria, primary IgA nephropathy, and C3 glomerulopathy when the medicine is not registered locally, with the mandatory REMS vaccination prerequisite as the defining intake step.

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, developed and commercialized by Novartis Pharmaceuticals Corporation. The US Food and Drug Administration approved Fabhalta on 5 December 2023 for paroxysmal nocturnal hemoglobinuria (PNH) in adults (the first oral monotherapy for PNH), on 8 August 2024 under accelerated approval for the reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, and on 20 March 2025 for C3 glomerulopathy (C3G) in adults (the first treatment for this rare kidney disease). In Egypt, Fabhalta is not registered with the Egyptian Drug Authority (EDA). Patients reach the medicine through EDA Personal Importation under Law No. 151 of 2019. Mandatory vaccination under the FABHALTA REMS programme is a label-defined prerequisite to initiation and is the dominant friction point in every case. Reserved for you.

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

Egypt has substantial adult haematology and nephrology programmes anchored at the major academic and private specialty centres in Cairo, Giza, and Alexandria, and the IgA nephropathy story is the meaningful Egyptian access angle. IgA nephropathy is one of the most common primary glomerular diseases worldwide and has been documented as a significant cause of chronic kidney disease progression in Egyptian renal series. Egyptian nephrologists managing IgAN have historically had limited disease-modifying options outside of RAS inhibition, SGLT2 inhibitors, sparsentan, and budesonide (Tarpeyo). Fabhalta is the first complement-targeted therapy approved for IgAN and addresses a different mechanism of action for patients at risk of rapid progression. PNH (1 to 2 per million population) and C3G (rarer still) are ultra-rare in the Egyptian context but well known to adult haematology and nephrology teams at Kasr Al Ainy and Ain Shams.

The Egyptian access gap is structural and falls into the third pattern of EDA filings: not registered locally at all. Fabhalta has European Medicines Agency centralized authorization (May 2024 for PNH; subsequent approvals for C3G; IgAN under review) and UK MHRA approval for PNH via the international recognition procedure. EDA has no current Fabhalta registration, and no local marketing authorization exists in any GCC or MENA market as of this page's review date. There is no local stock to dispense. Substitution is not a clinical match: for PNH, the alternatives are intravenous anti-C5 antibodies eculizumab (Soliris) and ravulizumab (Ultomiris), or the subcutaneous C3 inhibitor pegcetacoplan (Empaveli); Fabhalta is the first oral monotherapy. For IgAN, the alternatives are different-mechanism options; for C3G, no other FDA-approved disease-specific therapy exists.

3. The EDA named-patient pathway for Fabhalta

The Egyptian Drug Authority was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations under Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA is a public service authority affiliated to the Prime Minister and consolidates functions previously held by the National Organization for Drug Control and Research (NODCAR), the National Organization for Research and Control of Biopharmaceuticals

(NORCB), and the Ministry of Health's Central Administration of Pharmaceutical Affairs (CAPA). EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally. This is the pathway commonly referred to as Personal Importation, sometimes described in EDA correspondence as Special Access or Compassionate Use for unregistered drugs.

The standard application package for Fabhalta includes the clinical justification letter from the treating haematologist (for PNH) or nephrologist (for IgAN and C3G), on hospital letterhead, original and stamped, stating the indication-specific diagnosis with the appropriate diagnostic confirmation (for PNH, flow cytometry with PNH clone size on granulocytes and red cells; for IgAN, kidney biopsy with mesangial IgA deposits plus proteinuria at or above the FDA label threshold for risk of rapid progression; for C3G, kidney biopsy with C3-dominant features and exclusion of immune-complex disease), the prior therapies tried and failed, and the specific reason this product is required; a recent prescription specifying brand name (Fabhalta), generic name (iptacopan), strength (200 mg hard gelatin capsules), pack size (bottle of 60 capsules, a 30-day supply at twice-daily dosing), and quantity required; a patient identifier; the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference; product details (Novartis Pharmaceuticals Corporation as US NDA holder, country of origin, FDA approval references, room-temperature storage); the destination dispensing facility licence; a chain-of-custody plan from the US REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) through to the dispensing pharmacy in Egypt; and the documentation of completion or appropriate timing of vaccination against meningococcal (ACWY and B), pneumococcal, and Haemophilus influenzae type b organisms, per the FABHALTA REMS.

The clinical-justification angle that matters most for Fabhalta is the REMS vaccination evidence. The treating physician documents completion of meningococcal (ACWY and B), pneumococcal, and Hib vaccination at least 2 weeks before initiating therapy, or, where the risk of delay outweighs the infection risk, documents the appropriate antibiotic prophylaxis plan per the boxed warning. The letter references the APPLY-PNH and APPOINT-PNH 48-week data, the APPLAUSE-IgAN primary and 24-month results, and the March 2025 FDA approval as the first treatment for C3G. Routine EDA personal-import authorisations for well-documented haematology and nephrology cases are typically processed in a 3 to 6 week window once a complete package is submitted, with the vaccination workflow driving most of the elapsed time on a Fabhalta case. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

4. Where Fabhalta gets dispensed in Egypt

Fabhalta is an oral hard gelatin capsule, room-temperature stable at 20 to 25 degrees Celsius with permitted excursions between 15 and 30 degrees Celsius. It does not require infusion infrastructure, cold chain, or in-clinic administration. The dispensing requirement in Egypt is an EDA-licensed hospital outpatient pharmacy or licensed specialty importer, paired with an EMS-registered haematologist (for PNH) or nephrologist (for IgAN and C3G) supervising the case.

Egyptian institutions with established adult haematology and nephrology workflow capable of anchoring a Fabhalta case 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, dedicated adult haematology and nephrology units, and an institutional import workflow; Ain Shams University Hospitals, with strong oncology, hepatology, and adult haematology services; Dar Al Fouad Hospital in 6th of October City, Giza, a JCI-accredited private super-specialty hospital with the 1999 Cleveland Clinic cooperation agreement and active bone marrow transplant and adult haematology programmes; As-Salam International Hospital in Cairo; and the Cleopatra Hospitals Group, the largest private hospital group in Egypt. For physicians at smaller hospitals or outpatient clinics, the practical path is partnering with a Cairo-based licensed specialty importer that handles the EDA filing, customs clearance, and final delivery to the dispensing pharmacy where the haematologist or nephrologist follows the patient.

5. Real cost picture for Fabhalta in Egypt

Reserve Meds quotes Fabhalta cases in USD and accepts USD wire transfers. The EGP 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. Quoting in USD insulates the case from intra-case currency drift. Three line items frame the economics.

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 per Novartis pricing disclosures and Vermont 30-day reporting. This is the manufacturer-stated US list price before payer negotiation. Novartis copay support is US-only and does not extend to international named-patient cases. At the May 2026 EGP/USD rate, the WAC per 30-day fill corresponds to approximately EGP 2.4 million per fill and roughly EGP 29 to EGP 30 million per year.

Second, international logistics. Fabhalta is an ambient oral capsule. Standard express courier with full DSCSA documentation suffices; cold-chain insurance riders are not required. International logistics from the US source to Cairo International Airport typically runs USD 400 to USD 1,500 (approximately EGP 21,000 to EGP 80,000) depending on volume and route.

Third, vaccination cost and Egyptian regulatory documentation. The meningococcal (ACWY and B), pneumococcal, and Hib vaccinations themselves are a small but real line item incurred locally in Egypt and are generally not in scope for Reserve Meds. Egyptian regulatory documentation handling fees on the dispensing facility side vary by hospital and importer. The Reserve Meds concierge fee is itemised on the firm quote and never bundled. On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, MedGulf Egypt, Orient Takaful, and Royal Insurance each assess named-patient imports case by case. The Universal Health Insurance Authority (UHIA) does not currently cover most specialty imports. Cash-pay is the dominant posture, and many Egyptian families coordinate USD funds via relatives in the Gulf, the UK, or North America given the indefinite annual cost.

6. Typical timeline for Fabhalta in Egypt

Fabhalta is an ambient oral product, which removes the cold-chain transit window. The vaccination prerequisite is the dominant timeline driver. End-to-end, a typical Fabhalta case in Egypt runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 2 to 6 weeks for the treating physician to confirm or complete the meningococcal (ACWY and B), pneumococcal, and Hib vaccination protocol per the FABHALTA REMS and the most current ACIP recommendations for patients receiving complement inhibitors, with at least 2 weeks elapsed between final dose and Fabhalta initiation; in parallel, 5 to 10 days to assemble the EDA personal-import application with indication-specific diagnostic confirmation and the vaccination documentation; 3 to 6 weeks for routine EDA review; 3 to 5 days for US sourcing through the REMS-certified specialty pharmacy (Biologics by McKesson or Onco360), release documentation, and ambient courier shipment to Cairo International Airport; 1 to 2 days for customs clearance under the EDA authorisation; and final verification and dispense at the hospital outpatient pharmacy. Because Fabhalta is dosed twice daily on a chronic indefinite basis across all three indications, supply cadence is planned for repeat shipments from the first case.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA personal-import application for Fabhalta. The treating Egyptian specialist documents the indication-specific diagnosis: for PNH, flow-cytometry confirmation of PNH clone size on granulocytes and red cells, haemolytic anaemia evidence (haemoglobin, LDH, reticulocyte count), and prior anti-C5 history (eculizumab or ravulizumab) where applicable, with reference to APPLY-PNH and APPOINT-PNH data on transfusion independence and haemoglobin response; for primary IgA nephropathy, kidney biopsy with mesangial IgA deposits, proteinuria at or above the FDA label threshold for risk of rapid progression, and confirmation that the patient is on optimised supportive care with RAS inhibition; for C3 glomerulopathy, kidney biopsy with C3-dominant features and exclusion of immune-complex disease, with reference to the March 2025 FDA approval as the first treatment for C3G. The letter states the planned dosing regimen as 200 mg orally twice daily continuous (approximately 12 hours apart, swallowed whole, no loading dose), treatment chronic and indefinite. The letter explicitly documents the FABHALTA REMS vaccination prerequisite, with completion or appropriate timing of meningococcal (ACWY and B), pneumococcal, and Hib vaccinations at least 2 weeks before initiation, or, where the risk of delay outweighs the infection risk, the antibiotic prophylaxis plan.

The monitoring plan covers (1) clinical surveillance for signs of serious infection throughout therapy, with prompt evaluation of any fever or systemic symptoms, per the boxed warning for serious infections caused by encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae type b); (2) baseline and periodic liver function tests (ALT, AST, total bilirubin); (3) lipid monitoring per clinician judgement; and (4) patient education on infection-warning-sign recognition with provision of the patient safety card. CYP-interaction screening (avoid concomitant gemfibrozil as a strong CYP2C8 inhibitor; avoid strong CYP3A4 inducers) is performed at initiation and at every regimen change. The letter is co-filed with the physician's EMS membership and Ministry of Health licence reference, the dispensing facility licence, the requested pack and quantity (Fabhalta 200 mg capsules, bottle of 60, 30-day supply per bottle, packs sufficient for the planned coordination window), and the chain-of-custody plan from the US REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) through to the dispensing pharmacy in Egypt. Pharmacovigilance reporting through the Egyptian Pharmacovigilance Center (EPVC) using Yellow Card or CIOMS forms applies for the duration of therapy, with serious infection events receiving expedited reporting.

8. Common questions about Fabhalta in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, or Allianz cover the cost? Each insurer assesses named-patient imports case by case. Given the chronic and high annual cost of Fabhalta, partial reimbursement where coverage applies is meaningful. We supply the documentation an insurer needs to assess. The claim filing remains with the patient or the hospital.

Does UHIA cover specialty imports like Fabhalta? Not as a general rule. The Universal Health Insurance rollout under Law No. 2 of 2018 is phased through to 2032, with Cairo, Giza, and Qalyubia in the final phase. For most named-patient specialty imports in 2026, UHIA coverage is not the funding path.

Is the REMS vaccination requirement negotiable? No. Vaccination against meningococcal (ACWY and B), pneumococcal, and Hib organisms is a label-mandated prerequisite tied to the boxed warning for serious infections caused by encapsulated bacteria. The label permits initiation before completion of vaccinations only when the risk of delay outweighs the infection risk, with appropriate antibiotic prophylaxis. Reserve Meds requires documentation of the treating physician's vaccination plan before coordinating supply. This is the dominant intake-stage friction point on every Fabhalta case.

I have IgA nephropathy. Why Fabhalta and not Tarpeyo (budesonide), sparsentan, or RAS inhibition alone? Decisions across IgAN options rest with the treating nephrologist. Fabhalta is the first complement-targeted therapy approved for IgAN, addressing a different pathway than budesonide or sparsentan, and is positioned for patients at risk of rapid progression on optimised supportive care. The APPLAUSE-IgAN trial data support proteinuria reduction. Reserve Meds does not make the clinical recommendation. IgA nephropathy is a meaningful disease in the Egyptian renal population, and the Fabhalta route via personal importation is the operative path for patients whose nephrologist judges the addition appropriate.

I have PNH and I am stable on Soliris or Ultomiris. Should I switch? Switch decisions rest with the treating haematologist. APPLY-PNH demonstrated that two-thirds of patients with residual anaemia on eculizumab or ravulizumab achieved haemoglobin of 12 g/dL or higher without transfusion after switching to iptacopan, versus zero in the control arm. The oral route also avoids chronic intravenous or subcutaneous administration. Reserve Meds does not make the clinical recommendation.

Is Fabhalta a controlled substance? No. Fabhalta is not on the US DEA schedule and is not subject to controlled-substance import controls in Egypt. The standard EDA Personal Importation framework under Law No. 151 of 2019 applies.

9. Where Reserve Meds fits in Fabhalta cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating haematologist or nephrologist, EDA, your dispensing pharmacy, or your insurer, and we do not act as an importer of record in Egypt. 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

Novartis prescribing information, the FABHALTA REMS vaccination requirement and ACIP-aligned vaccination resource, the indication-specific diagnostic criteria (flow cytometry for PNH; kidney biopsy with C3-dominant features for C3G; kidney biopsy with mesangial IgA deposits plus proteinuria documentation for IgAN), and the EDA Personal Importation application format; align the US-side sourcing through DSCSA-compliant REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) with the Egyptian dispensing facility; coordinate the ambient courier shipment under chain-of-custody documentation to Cairo International Airport; and provide a single named coordinator across the case, in Arabic on the patient side and English on the family side where the family is split across the diaspora. Because Fabhalta is chronic and indefinite across all three indications, Reserve Meds plans annual supply discussions and repeat-shipment cadence from the first case, with the REMS vaccination evidence treated as the gating intake step. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Egyptian haematologist or nephrologist has confirmed PNH, primary IgA nephropathy at risk of rapid progression, or C3 glomerulopathy and recommends Fabhalta, 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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