Fabhalta access in India: the CDSCO Rule 36 named-patient pathway

How patients in India access Fabhalta (iptacopan) for paroxysmal nocturnal hemoglobinuria, primary IgA nephropathy, and C3 glomerulopathy when the medicine is not yet locally registered, including the mandatory 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. 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 India, Fabhalta is not yet registered with the Central Drugs Standard Control Organization (CDSCO). Patients reach the medicine through Rule 36 of the Drugs and Cosmetics Rules 1945, with the office of the Drugs Controller General of India (DCGI) issuing Form 12B against a complete Form 12A application. 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 India patients need Fabhalta via the named-patient pathway

India has the largest tertiary specialty hospital network of any Reserve Meds priority country, with strong adult haematology and nephrology programmes at the apex institutions. Yet Fabhalta sits firmly in the third pattern of access gap that drives CDSCO Rule 36 demand: 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. CDSCO has no current Fabhalta registration, and there is no local stock to dispense.

IgA nephropathy is the meaningful Indian access story. IgA nephropathy is one of the most common primary glomerular diseases worldwide, and Indian nephrology series have repeatedly identified it as a significant cause of chronic kidney disease progression in Indian patients. Until Fabhalta, disease-modifying options were limited to RAS inhibition (ACE/ ARB), SGLT2 inhibitors, sparsentan, and budesonide (Tarpeyo). Fabhalta is the first complement-targeted therapy approved for IgAN, providing Indian nephrologists with a new mechanism of action for patients at risk of rapid progression. The Indian Society of Nephrology and the Renal Pathology Society in India have flagged complement-pathway IgAN as an active area of clinical interest. PNH (1 to 2 per million population) and C3G (rarer still) are ultra-rare in the Indian context but well known to adult haematology and nephrology teams at AIIMS, Tata Memorial, Apollo, and CMC Vellore. For all three indications, substitution to a domestic alternative is not a clinical option once the underlying diagnosis (flow-cytometry-confirmed PNH or biopsy-confirmed IgAN or C3G) and the indication-specific risk criteria are documented.

3. The CDSCO Rule 36 named-patient pathway for Fabhalta

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity of a drug for the exclusive personal use of a named patient, with the legal basis sitting under Section 10 of the Drugs and Cosmetics Act 1940.

Form 12A is the application for a permit, made under the second proviso to Rule 36. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) whose National Medical Commission (NMC) registration number appears on the prescription, with the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For institutional Compassionate Use where the drug is not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route is used where the drug is approved by a recognised reference authority such as the FDA for a life-threatening condition or a serious permanent disability. PNH, progressive IgAN, and C3G all fit the criteria, and AIIMS and Tata Memorial Centre have established workflow for this pathway.

A complete CDSCO application for Fabhalta typically includes:

- A clinical justification letter (indication, diagnostic confirmation appropriate to the indication, prior therapies tried and failed, the specific reason this product is required)
- The treating haematologist's or nephrologist's NMC registration number and state-council registration where required
- A patient identifier and supporting medical records (flow cytometry for PNH; kidney biopsy with C3-dominant features for C3G; kidney biopsy with mesangial IgA deposits plus proteinuria documentation for IgAN)
- Product details: Fabhalta, iptacopan, Novartis Pharmaceuticals Corporation, 200 mg capsules, bottle of 60 (30-day supply at twice-daily dosing)
- The dispensing facility's drug licence (hospital outpatient pharmacy with REMS-channel access or specialty importer's wholesale licence)
- A chain-of-custody plan from the US REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) through to the dispensing pharmacy in India
- 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. CDSCO published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications. In practice, the vaccination workflow drives most of the elapsed time on a Fabhalta case.

4. Where Fabhalta gets dispensed in India

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 is a CDSCO-licensed hospital outpatient pharmacy or licensed specialty importer, paired with an NMC-registered haematologist (for PNH) or nephrologist (for IgAN and C3G) supervising the case.

Indian tertiary institutions with established haematology and nephrology workflow include the All India Institute of Medical Sciences (AIIMS), New Delhi, the apex public-sector institution and a designated Centre of Excellence under the National Policy for Rare Diseases; Tata Memorial Centre, Mumbai, India's largest cancer institute and anchor of the National Cancer Grid with associated adult haematology programmes; Apollo Hospitals at Chennai, Delhi, Bangalore, Hyderabad, and Kolkata with dedicated international patient services and adult nephrology and haematology departments; Fortis Memorial Research Institute, Gurgaon, and Fortis Healthcare sites at Mumbai, Bangalore, and Kolkata; Medanta The Medicity, Gurgaon, with established multi-superspecialty programmes; Kokilaben Dhirubhai Ambani Hospital, Mumbai; Christian Medical College (CMC) Vellore, globally recognised for haematology and nephrology, with one of India's longest-running renal pathology services; and Manipal Hospitals, Bangalore. PGIMER Chandigarh and SGPGIMS Lucknow are additional recognised nephrology centres.

For physicians at smaller institutions without an import pharmacy desk, the practical route is to work with one of the centres above, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing and the chain-of-custody documentation on behalf of the prescribing specialist.

5. Real cost picture for Fabhalta in India

Costs sit in INR with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. Three line items frame the case 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. That corresponds to roughly INR 43.7 to INR 44.2 lakh per 30-day fill and approximately INR 5.3 crore per year at the prevailing exchange rate. 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.

Second, international logistics. Fabhalta is an ambient oral capsule. International logistics for an ambient shipment to India typically runs USD 400 to USD 1,500 (approximately INR 38,000 to INR 1.4 lakh) depending on destination city and urgency window. No gel packs, no temperature loggers, no quarantine risk.

Third, regulatory and coordination. India's Union Budget 2026-27 added rare-disease conditions to the duty-free personal-import list and expanded customs duty exemptions. GST on most life-saving medicines is 5 percent. The specific HSN code and exemption status of each Fabhalta shipment is confirmed at the documentation stage. The vaccination cost itself (meningococcal ACWY and B, pneumococcal, Hib) is a small but real line item incurred locally in India and is generally not in scope for Reserve Meds. On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa each assess named-patient imports case by case and none reimburses a Rule 36 personal import as a standard line item. CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS) on a case-by-case basis, with stricter constraints on drugs not approved by DCGI. The National Policy for Rare Diseases 2021 framework provides one-time financial assistance up to INR 50 lakh per patient under the Rashtriya Arogya Nidhi for designated Centres of Excellence, which is meaningful for PNH and C3G as recognised rare diseases but is structurally short of the lifetime cost of chronic complement-inhibitor therapy. Cash-pay is the default posture.

6. Typical timeline for Fabhalta in India

CDSCO's published guidance states the Form 12B permit is issued on a priority basis, typically within one to two days for routine applications where the documentation is complete. 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 India 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 Form 12A application with indication-specific diagnostic confirmation and the vaccination documentation; one to two business days for routine DCGI review; 3 to 5 days for US sourcing through the REMS-certified specialty pharmacy, release documentation, and ambient courier shipment; 1 to 2 days for customs clearance under the Form 12B permit; and final verification and dispense at the hospital 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 Form 12A application for Fabhalta. The treating Indian specialist documents the indication-specific diagnosis: for PNH, flow-cytometry confirmation of PNH clone size on granulocytes and red cells, hemolytic 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), with 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; (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.

The letter is co-filed with the physician's NMC registration number and state-council registration where required, the dispensing facility's drug 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, capped at one hundred average doses per Form 12A application), and the chain-of-custody plan describing how the medicine will move from the US REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) through to the hospital pharmacy. Pharmacovigilance Programme of India (PvPI) reporting through the Indian Pharmacopoeia Commission applies for the duration of therapy and is the prescribing physician's obligation, with serious infection events receiving expedited reporting.

8. Common questions about Fabhalta in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover the cost? Each insurer assesses named-patient rare-disease imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item. We supply the documentation; the claim itself is filed by the patient or the hospital.

Will my CGHS, ESIC, or NPRD entitlement cover this? CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case, with stricter constraints on drugs not approved by DCGI. The National Policy for Rare Diseases 2021 framework provides one-time financial assistance up to INR 50 lakh per patient at designated Centres of Excellence under Rashtriya Arogya Nidhi for recognised rare diseases such as PNH and C3G, but is structurally short of the lifetime cost of chronic complement-inhibitor therapy. ESIC's formulary is narrower. Check eligibility with the relevant scheme before assuming coverage.

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 (Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae type b). 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.

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.

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 a controlled substance under Indian law. Narcotics Control Bureau coordination does not apply. The standard Rule 36 Form 12A and Form 12B permit is the operative framework.

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, the DCGI, the dispensing hospital pharmacy or licensed importer, 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 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 Form 12A application format; align the US-side sourcing through DSCSA-compliant REMS-certified specialty pharmacy (Biologics by McKesson or Onco360) with the Indian hospital pharmacy or specialty importer; coordinate the ambient courier shipment under chain-of-custody documentation; and provide a single named coordinator across the case, regardless of how many Indian cities the family touches. 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 Indian 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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