Fabhalta

Dubai · access guide

How to access Fabhalta from Dubai, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A the UAEi patient with paroxysmal nocturnal hemoglobinuria (PNH) may be evaluated by their treating haematologist for Fabhalta (iptacopan). Fabhalta is FDA-approved in the United States and manufactured by Novartis. It is the first oral monotherapy for PNH and a first-in-class factor B inhibitor, acting on the alternative complement pathway. Fabhalta is rarely locally registered outside the US and EU, and for the UAEi patients the named-patient import pathway via the Dubai Ministry of Public Health (MoPH) is the legitimate route.

This guide explains the pathway, what documentation your physician needs, typical costs and timing, and where Reserve Meds fits in.

The clinical situation

Fabhalta is administered as an oral capsule twice daily. It targets factor B in the alternative complement pathway, addressing both intravascular and extravascular haemolysis. Like other complement pathway inhibitors, it carries a US class-level warning about encapsulated-organism infections; vaccination (meningococcus, pneumococcus, Hib) is a gating step before therapy. Your treating haematologist confirms PNH diagnosis (flow cytometry), prior therapy history, vaccination completion, and the monitoring plan per FDA labeling.

Is Fabhalta legally importable into the Dubai?

Yes, through the Dubai Ministry of Public Health (MoPH) Pharmacy & Drug Control Department named-patient framework. The pathway allows a the Dubai-licensed (under DHA) physician to import a medicine not locally registered when: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent registered alternative fits, (c) the physician takes clinical responsibility, and (d) chain of custody is documented.

For oral complement-pathway inhibitors, the named-patient route is the standard mechanism in the UAEi tertiary haematology, Fabhalta is not yet on a local formulary.

How the pathway works, step by step

1. **Consultation with your treating haematologist.** PNH flow cytometry confirmation, prior therapy history, and clinical rationale.
2. **Pre-treatment vaccination.** Meningococcal, pneumococcal, and Hib vaccinations per labeling.
3. **MoPH named-patient application.** The physician or hospital pharmacy files the application.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner.
5. **Shipment.** Fabhalta is an oral capsule with standard storage; shipment includes tamper-evident packaging and chain-of-custody documentation.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription.

What documentation your physician needs

Your physician will typically need to provide:

- Clinical rationale letter confirming PNH, diagnostic evidence (flow cytometry), prior therapies, and Fabhalta as the indicated treatment
- Verification of their the DHA medical licence (Dubai emirate)
- Patient identifier
- Vaccination documentation
- Planned twice-daily oral regimen and monitoring cadence

Reserve Meds provides a physician documentation kit that bundles the templates MoPH reviewers expect to see for complement-pathway inhibitors.

Costs and timing

Fabhalta's US cash-pay drug-only reference price for a 30-day supply sits in a broad indicative range of roughly USD 38,000-45,000. International logistics, MoPH documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a full transparent quote at the start of intake. Indicative range.

Indicative timing for first dose after cohort intake opens is 7-14 days from the moment a complete application is submitted, plus vaccination lead time. Refills ship on a rolling basis.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Fabhalta specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and for MoPH review.
- **Logistics.** Tamper-evident, internationally tracked shipment.
- **Concierge case lead.** A named point of contact.

What we do not do: we are not the prescriber, we do not practise medicine, and we are not the dispensing pharmacy. All clinical decisions remain with your treating haematologist.

Frequently asked

Is this legal in Dubai? Yes, when executed through the MoPH named-patient framework with appropriate documentation.

Why Fabhalta rather than a C5 or C3 inhibitor? Fabhalta's oral route is a major quality-of-life factor, no infusions or subcutaneous injections. Efficacy data support its use as monotherapy in PNH, including in patients with persistent anaemia on C5 inhibition. Your haematologist will decide.

What about the vaccination requirement? It is load-bearing. Encapsulated-organism vaccination per labeling is completed before therapy starts.

Will private insurance cover this? Cash-pay is the default. Some the UAEi insurers reimburse named-patient imports for ultra-rare-disease therapies on escalated review; we supply documentation for your submission but do not process insurance claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

reservemeds.com · hello@reservemeds.com