

Fabrazyme

Oman · access guide

How to access Fabrazyme from Oman, the named-patient import pathway, 2026

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

A Oman patient with confirmed Fabry disease may receive a prescription for Fabrazyme (agalsidase beta) from their treating metabolic specialist, nephrologist, or cardiologist as enzyme-replacement therapy. Fabrazyme is FDA-approved in the United States for long-term treatment of Fabry disease. In the Kingdom of Oman, Fabrazyme may not always be uniformly stocked across tertiary metabolic centres, which is why your specialist may be coordinating a named-patient import pathway on your behalf for ongoing infusion supply.

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

The clinical situation

Fabrazyme is an intravenous enzyme-replacement therapy (recombinant human alpha-galactosidase A) administered as an infusion once every two weeks. Eligibility requires biochemical and/or genetic confirmation of Fabry disease. The manufacturer is Sanofi (Genzyme). Dosing is typically 1 mg/kg IV every two weeks. The product requires refrigerated storage (2-8 degrees C) and reconstitution before infusion. Monitoring includes renal function, cardiac parameters (LV mass, ECG), infusion-reaction surveillance, and antibody response. Your specialist will confirm Fabry diagnosis and coordinate the infusion plan.

Is Fabrazyme legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient import framework. The Oman has a mature named-patient mechanism that has supported cross-border access to rare-disease enzyme-replacement therapies for many years.

The DGPADC named-patient route allows a Oman-licensed physician to request import of a medicine that is not locally registered when: (a) the medicine has been approved by a recognised reference authority (FDA qualifies), (b) there is no clinically equivalent locally registered alternative, (c) the treating physician takes clinical responsibility for use, and (d) the importing party documents chain of custody from the US source to the administering facility. Because Fabrazyme is cold-chain, chain-of-custody documentation includes continuous temperature logging.

How the pathway works, step by step

1. **Consultation with your treating specialist.** The decision to prescribe Fabrazyme is clinical, based on Fabry confirmation and organ-system burden. Your specialist documents the rationale.
2. **Infusion-facility identification.** A Oman tertiary hospital or infusion centre equipped for bi-weekly enzyme-replacement infusions accepts the case.
3. **DGPADC named-patient application.** Your physician or the hospital's importing pharmacy files an application with DGPADC including clinical rationale, patient identifier, product details, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from the manufacturer's authorised distribution chain under DSCSA.
5. **Cold-chain shipment.** Fabrazyme travels with validated cold-chain packaging and continuous temperature logging end to end.
6. **Arrival and infusion.** The infusion centre receives the product and administers under your specialist's care. Reserve Meds coordinates the next cycle ahead of depletion.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming Fabry diagnosis, organ-system status, and Fabrazyme as the indicated therapy
- Verification of their Oman medical licence (SCFHS / MOH)
- A current prescription naming the product, dose (mg/kg), and infusion schedule
- Patient identifier (anonymised reference preferred)
- The identified infusion facility and its cold-chain handling capability

Reserve Meds provides a physician documentation kit bundling the templates DGPADC reviewers expect to see for named-patient import of cold-chain enzyme-replacement therapies.

Costs and timing

Fabrazyme's US cash-pay drug-only reference price is weight-dependent. A typical adult annual cost sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 300,000-450,000 for ongoing bi-weekly infusions. Logistics, DGPADC documentation handling, cold-chain shipment, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake.

Indicative timing for first shipment arrival after cohort intake opens is 7-14 days from the moment a complete DGPADC application is submitted. Subsequent cycles are scheduled to match the bi-weekly infusion calendar.

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.

A brief culturally-aware note: Ramadan and Hajj seasons can affect scheduling across Oman tertiary centres. Our concierge team coordinates infusion timing with your family's preferences and your hospital's calendar.

Reserve Meds's role

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

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody.
- **Documentation.** Regulatory documentation package for your physician and for DGPADC review.
- **Logistics.** Cold-chain shipment and chain-of-custody coordination with temperature logging.
- **Concierge case lead.** A named point of contact for your family and your physician throughout the process.

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 specialist and the infusion facility.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC named-patient framework with appropriate documentation. The pathway has been used routinely across rare disease for many years. See our trust and compliance page.

What if the cold chain breaks? Our protocol logs temperature continuously; any excursion is assessed against manufacturer stability data. If the product is compromised, we re-source at our cost per service terms.

Is Fabrazyme different from Elfabrio or Replagal? Yes, different molecules (agalsidase beta vs alfa vs PEGylated). Choice and switching is a clinical decision by your specialist. We do not influence choice.

Will private insurance cover this? Cash-pay is the default. Some Oman private insurers reimburse named-patient imports on case-by-case approval; 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.

Reserve Meds

reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.

Reserve Meds is in pre-launch. Published timelines and cost ranges are indicative, not guarantees.

reservemeds.com · hello@reservemeds.com