Elfabrio

Oman · access guide

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

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

A Oman patient diagnosed with Fabry disease may receive a prescription for Elfabrio (pegunigalsidase alfa) from their treating metabolic-disease specialist, nephrologist, cardiologist, or geneticist, working with a multidisciplinary Fabry clinic in Abu Dhabi, Dubai, or Sharjah. Elfabrio is FDA-approved enzyme replacement therapy (ERT) for Fabry disease and is co-developed by Chiesi and Protalix. It is a PEGylated recombinant alpha-galactosidase A, designed to extend plasma half-life relative to the earlier ERT generation. Elfabrio is not routinely stocked through Oman domestic supply chain for this indication, so access typically runs through the named-patient import pathway.

This guide explains the legal pathway, the documentation your specialist prepares, typical timing, indicative cost posture, and where Reserve Meds fits in.

The clinical situation

Elfabrio is an intravenous PEGylated enzyme replacement therapy administered once every two weeks by infusion. It delivers exogenous alpha-galactosidase A to clear accumulated globotriaosylceramide (Gb3) in patients with Fabry disease, regardless of GLA mutation type, an important distinction from the oral chaperone Galafold, which is labelled only for amenable mutations. Eligibility is anchored in a confirmed Fabry diagnosis (biochemical GLA enzyme activity and / or GLA genetic testing) and specialist-led management. Your physician will establish baseline renal function (eGFR, urine albumin:creatinine), cardiac workup (echocardiogram, ECG, cardiac MRI where indicated), lyso-Gb3, a Fabry-specific symptom inventory, and an infusion-capable centre. Elfabrio infusions are typically given over 1-3 hours with pre-infusion observation protocols, and home infusion may be an option at select Oman centres after the initial in-hospital cycles.

Is Elfabrio legally importable into Oman?

Yes, through the Directorate General of Pharmaceutical Affairs and Drug Control (DGPADC) named-patient import framework, with parallel authority operated by the Department of Health (DoH) in Abu Dhabi and the Dubai Health Authority (DHA) in Dubai depending on where the prescribing facility sits.

The named-patient mechanism permits a Oman-licensed physician to import a medicine not locally registered when (a) it is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent locally available alternative suits the specific patient, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented end-to-end. Fabry disease has limited disease-specific registered options on Oman formularies, which supports clinical rationale.

How the pathway works, step by step

1. **Consultation with your treating specialist.** GLA enzyme activity and/or genetic report, Fabry symptom inventory, and a clinical rationale letter.
2. **Baseline assessment.** Renal function (eGFR, urine albumin:creatinine), cardiac workup, lyso-Gb3, Fabry symptom inventory, and identification of an infusion-capable centre.
3. **DGPADC named-patient application.** The physician or hospital pharmacy files clinical rationale, patient reference, every-two-week dosing plan, and chain-of-custody commitment.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Elfabrio from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Elfabrio requires refrigerated handling; shipment follows validated cold-chain protocols with temperature logging.
6. **Arrival and infusion.** The hospital pharmacy receives the product; the infusion centre administers the dose every two weeks, with pre-infusion observation protocols.

What documentation your physician needs

- Clinical rationale letter confirming Fabry disease and Elfabrio as the indicated therapy
- Verification of Oman medical license
- GLA enzyme activity and/or genetic test result
- Baseline renal function (eGFR, urine albumin:creatinine)
- Baseline cardiac workup (echocardiogram, ECG, cardiac MRI where indicated)
- Lyso-Gb3 and Fabry symptom inventory
- Planned dosing schedule (IV every 2 weeks) and infusion-centre identification
- Prior ERT history if the patient is switching from Fabrazyme or Replagal

Reserve Meds provides a physician documentation kit bundling the templates DGPADC reviewers expect for rare-disease ERT named-patient imports.

Costs and timing

Elfabrio for Fabry disease is a long-duration chronic infusion therapy. Reference US cash-pay for an annual course of every-two-week infusions typically sits in the high six to seven-figure USD range depending on patient weight (dosing is weight-based). Reserve Meds operates on a drug-only reference basis and provides a transparent, itemised delivered quote, covering product, cold-chain logistics, DGPADC documentation handling, customs clearance, and concierge coordination, at the start of intake. Figures are indicative, not a binding quote until intake is complete.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete DGPADC application is submitted. Every-two-week infusion cadence is established with the infusion centre thereafter.

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

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and DGPADC / DoH / DHA review.
- **Logistics.** Validated cold-chain shipment to your prescribing hospital pharmacy or infusion centre.
- **Concierge case lead.** A named point of contact coordinating the every-two-week infusion cadence.

What we do not do: We are not the prescriber. We do not practise medicine. We are not the dispensing pharmacy. All clinical decisions, including infusion administration and pre-infusion management, remain with your treating specialist and the infusion centre.

Frequently asked

Is this legal in Oman? Yes, when executed through the DGPADC / DoH / DHA named-patient framework with appropriate documentation. See our trust and compliance page.

How is Elfabrio different from Fabrazyme or Replagal? All three are alpha-galactosidase A enzyme replacement therapies for Fabry disease. Elfabrio is PEGylated, with a longer plasma half-life and differing immunogenicity profile relative to the earlier generation. Head-to-head clinical data (including the BALANCE and BRIDGE trials) inform switching and de-novo decisions, which your specialist will interpret for your case.

How is Elfabrio different from Galafold? Elfabrio is IV enzyme replacement therapy usable regardless of GLA mutation. Galafold is an oral chaperone labelled only for patients with amenable GLA variants. Patients with non-amenable mutations are typically routed to ERT (Elfabrio, Fabrazyme, or Replagal); patients with amenable variants may choose between ERT and Galafold under specialist guidance.

Can Elfabrio infusions be done at home? Some Oman centres support home infusion after the initial in-hospital cycles establish tolerance. Your specialist will advise.

Will insurance cover this? Cash-pay is the default. Some Oman private insurers consider rare-disease ERT imports case by case; 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.

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.
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