

Elfabrio

Dubai · access guide

Elfabrio (pegunigalsidase alfa-iwxj) for a Dubai-based adult with Fabry disease: what the pathway looks like in 2026

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

A Dubai-resident adult with Fabry disease has the conversation about Elfabrio in an emirate with deep adult internal medicine and cardiology infrastructure but with the deepest UAE genetics depth concentrated cross-emirate in Abu Dhabi. The Dubai Genetic Diseases Programme at Dubai Hospital, the cardiology institutes at Mediclinic City and American Hospital Dubai, and Cleveland Clinic Abu Dhabi (cross-emirate) are the operational anchors. Many Dubai Fabry patients are managed in a hybrid pattern: the diagnostic and metabolic-specialist conversation cross-emirate in Abu Dhabi at SKMC or Cleveland Clinic Abu Dhabi, ongoing infusion delivery in Dubai, and cardiac and renal surveillance distributed across both emirates.

This page is the first honest read on Elfabrio in Dubai, written by the team that would coordinate around your treatment plan if you decided you wanted operational support on the workup, the choice among the three Fabry ERTs, the EDE filing and DHA emirate-level layer, the cross-emirate MDT alignment, and the long-term cost picture.

What Fabry disease is, in plain terms

Fabry disease is an X-linked lysosomal storage disorder. Deficient alpha-galactosidase A activity allows globotriaosylceramide (Gb3) to accumulate in lysosomes across vascular endothelium, kidney podocytes, cardiomyocytes, and dorsal root ganglia neurons. The accumulation causes the multisystemic disease.

Classic Fabry presents in childhood with burning hand and foot pain, heat and cold intolerance, reduced sweating, gastrointestinal pain, and angiokeratomas. Renal failure, hypertrophic cardiomyopathy, and cerebrovascular events emerge in adulthood. Untreated life expectancy in classic males is reduced by approximately 20 years.

Later-onset and variant phenotypes present in middle adulthood with cardiac or renal involvement. Female heterozygotes can be severely affected because of X-inactivation. The "carrier" framing undersells the clinical reality for many women.

The X-linked inheritance pattern means cascade testing of first-degree relatives is part of standard care.

The diagnostic prerequisite that has to be in place

You cannot start Elfabrio without confirmed Fabry disease:

Enzyme assay. Alpha-galactosidase A activity in leukocytes or dried blood spot. Diagnostic in classic-Fabry males; not reliable in female heterozygotes.

GLA gene sequencing. Primary diagnostic tool in females; confirmatory in males. Informs the migalastat amenability question.

Supporting biomarker: lyso-Gb3.

Baseline organ assessment: echocardiogram with strain imaging, cardiac MRI with T1 mapping (Mediclinic City has the depth), eGFR, albuminuria, audiology, ophthalmology (cornea verticillata), neurological screen, brain MRI.

Dubai Hospital's Dubai Genetic Diseases Programme handles the enzyme assay and GLA sequencing through in-house and reference-laboratory pathways. Cross-emirate to SKMC Abu Dhabi or Cleveland Clinic Abu Dhabi is the typical route for the deepest metabolic-specialist consultation. Mediclinic City's cardiology depth and American Hospital Dubai's adult internal medicine handle the cardiac and general adult management. Amenability testing for migalastat is routed to an international Fabry reference laboratory.

Where Elfabrio sits among the alternatives

Three commercial Fabry ERTs plus an oral alternative:

Agalsidase alfa (Replagal, Takeda): 0.2 mg/kg q2w IV, ~40 min infusion, CHO-derived. **Agalsidase beta (Fabrazyme, Sanofi):** 1 mg/kg q2w IV, CHO-derived. **Elfabrio (Chiesi/Protalix):** 1 mg/kg q2w IV, plant-cell-expressed, PEG-modified, FDA approved May 2023. **Migalastat (Galafold, Amicus):** oral pharmacological chaperone for amenable GLA mutations.

The BALANCE trial showed non-inferiority of Elfabrio to agalsidase beta on annualised eGFR slope over 24 months. The treating geneticist makes the call based on patient-specific factors.

The Dubai regulatory pathway: how it actually works in 2026

The Emirates Drug Establishment (federal) plus the Dubai Health Authority (emirate-level) form the Dubai pathway. Where Elfabrio holds formal UAE registration, standard prescription and import procurement applies. Where not, the EDE named-patient mechanism is filed by the hospital's import pharmacy on the treating geneticist's behalf, with DHA layering its own approval. [VERIFY: EDE Elfabrio 2026 registration status]

DHA-licensed private hospitals (American Hospital Dubai, Mediclinic City, Mediclinic Parkview, NMC Specialty, Saudi German Hospital Dubai, Dr Sulaiman Al Habib network) handle insurance pre-authorisation through the DHA framework. Dubai Hospital (public) handles the public-sector pathway for Emirati nationals and DHA-eligible expatriates.

In our experience coordinating recent-FDA-approval rare-disease ERTs in Dubai, timeline from filing to first infusion runs three to six weeks. For Elfabrio specifically, the variables are antibody-status documentation (if switching from Fabrazyme or Replagal) and the cross-emirate MDT alignment with the geneticist in Abu Dhabi.

The realistic Dubai infrastructure for adult Fabry ERT: - **Dubai Hospital**. Dubai Genetic Diseases Programme. Public-sector home for Fabry workup and follow-up. - **American Hospital Dubai**. Adult internal medicine, infusion-suite capability. - **Mediclinic City Hospital**. Cardiology depth relevant to Fabry cardiac phenotype; infusion-suite capability. - **Mediclinic Parkview**. Adult internal medicine and infusion suite. - **NMC Specialty Hospital, Saudi German Hospital Dubai, Dr Sulaiman Al Habib**. Private-sector adult care; infusion delivery; coordinate with cross-emirate geneticist. - **Cross-emirate SKMC, SSMC, Cleveland Clinic Abu Dhabi**. Deepest metabolic-specialist and genetics depth; commonly the home for the diagnostic and treatment-choice conversations even when ongoing infusion is delivered in Dubai.

Reserve Meds coordinates the cross-emirate logistics and the documentation packet that lets the DHA-side infusion centre deliver against the Abu Dhabi-side geneticist's plan.

The access pathway in Dubai: step by step

1. Diagnostic confirmation (enzyme assay plus GLA sequencing) at Dubai Hospital or cross-emirate at SKMC or Cleveland Clinic Abu Dhabi; migalastat amenability check via international reference laboratory.
2. Clinical geneticist consultation (typically cross-emirate at SKMC, SSMC, or Cleveland Clinic Abu Dhabi) with the documentation packet from Reserve Meds.
3. Baseline multidisciplinary organ assessment: cardiac (Mediclinic City strong on echo and MRI), renal (eGFR, albuminuria), neurological, audiology, ophthalmology.
4. ERT choice decision with the treating geneticist. Antibody testing if switching.
5. EDE plus DHA filing through the Dubai infusion centre's import pharmacy.
6. First Elfabrio infusion at the Dubai infusion centre (American Hospital Dubai, Mediclinic City, or partner site). Premedication titrated based on infusion-reaction history.
7. Stable every-2-week infusion routine over the next 2 to 3 months. Subsequent infusions can shorten from approximately 3 hours to approximately 1.5 hours.
8. Ongoing surveillance: biomarkers and antibody titre at intervals, eGFR every 3 months, annual echocardiogram, periodic cross-emirate geneticist follow-up.

The cost conversation, in the form a Dubai family needs

The 2026 indicative annual list price of Elfabrio is approximately USD 350,000 to USD 400,000 per year for an average-weight adult, or approximately AED 1.29 million to AED 1.47 million per year. Over a multi-decade therapy course, cumulative drug cost can reach USD 10 to 20 million, before counting cardiac and renal supportive care.

For Emirati nationals being treated at Dubai Hospital under the public system or with Thiqa coverage cross-emirate, much of the cost may be underwritten through government health funding pathways. For expatriate residents on DHA-mandated insurance, the cost picture depends on the specific plan; rare-disease and high-cost-biologic riders vary widely. We separate every line in the intake quote: drug per infusion, infusion-suite charges, premedication, antibody and biomarker labs, cardiac and renal surveillance, our coordination fee. Nothing is bundled.

Insurance pre-authorisation in Dubai for Elfabrio specifically often requires the geneticist's letter documenting why Elfabrio rather than Fabrazyme is the recommended choice. We supply the insurer with the documentation packet at no charge.

What to monitor on Elfabrio

- Lyso-Gb3 and Gb3 biomarkers at 6-month intervals. - Anti-drug antibody titre at intervals (ADAs in ~50 percent of patients). - eGFR and albuminuria every 3 months. - Echocardiogram annually, more often based on cardiac phenotype. - Neurological reassessment annually. - Audiology and ophthalmology annually. - Infusion-associated reaction surveillance at every infusion. - Membranous glomerulonephritis surveillance through urine protein.

Mental-health screening. Fabry disease carries a meaningful psychosocial burden. Chronic neuropathic pain, progressive cardiac and renal disease, X-linked family-planning weight, and the diagnostic-delay history many patients carry all contribute. PHQ-9 screening at baseline and at routine intervals is appropriate; C-SSRS where clinical concern arises. Psychiatry or clinical psychology referral should be a standing option in the multidisciplinary care plan, not a crisis-only afterthought.

Religious-ethical considerations

Elfabrio is produced in plant cell culture (tobacco) and PEG-modified. Not animal-derived and not plasma-derived. The plant-cell origin is simpler from a halal framing perspective than mammalian-cell products in some interpretations. Sunni and Shia bioethics consensus on life- and function-preserving therapies is broadly permissive. Families typically consult with their religious advisors before committing.

For Dubai Fabry families weighing cascade testing for first-degree relatives, the genetic counselling pathway runs through the Dubai Genetic Diseases Programme at Dubai Hospital or cross-emirate at SKMC.

When Elfabrio is not the right answer

For patients with an amenable GLA mutation, oral migalastat is the alternative.

For patients stable on Replagal or Fabrazyme with good response and no antibody-related issues, switching to Elfabrio is not automatic.

For patients with very advanced cardiac or renal disease, the conversation includes whether ERT will meaningfully alter the trajectory or whether supportive care is the more meaningful intervention.

What Reserve Meds does, and what we do not do

Reserve Meds is a US-based concierge coordinator. For a Dubai-resident adult pursuing Elfabrio, our scope is the diagnostic-confirmation pathway routing, the cross-emirate MDT documentation packet, the EDE plus DHA filing in collaboration with the Dubai infusion centre's import pharmacy, the sourcing logistics from Chiesi's authorised distribution through DSCSA-compliant chain of custody, cold-chain shipment to the qualified Dubai centre, and named case-lead coordination from intake through the establishment of a stable every-2-week infusion routine.

Reserve Meds is not your prescriber. We do not practise medicine. We do not own or operate the infusion centre. We are not your insurer. Clinical decisions stay with your geneticist (typically cross-emirate in Abu Dhabi) and the Dubai infusion centre team.

We work cash-pay where applicable. Our coordination fee is disclosed in writing.

What to do if you want to start

The first concrete step is a call with our case-lead so we can confirm where you are in the diagnostic and clinical picture, and whether the right next move is the diagnostic confirmation, the cross-emirate geneticist consultation, or the EDE filing.

Most patients reach us first on WhatsApp.

Start your treatment plan on the portal, or open a WhatsApp conversation with the case-lead and we will take it from there.

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.

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