Vimizim

Saudi Arabia · access guide

How to access Vimizim from Saudi Arabia, the named-patient import pathway, 2026

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

A Saudi Arabiaian patient with Morquio A syndrome (mucopolysaccharidosis type IVA, MPS IVA), an inherited lysosomal storage disorder affecting bone and connective tissue, may receive a prescription for Vimizim (elosulfase alfa) from their treating metabolic specialist or paediatric geneticist as enzyme-replacement therapy. Vimizim is FDA-approved in the United States for long-term treatment of Morquio A. In Saudi Arabia, Vimizim may not always be routinely stocked locally, which is why your specialist may be coordinating a named-patient import pathway on your behalf for ongoing weekly 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

Vimizim is an intravenous enzyme-replacement therapy (recombinant human N-acetylgalactosamine-6-sulfatase) administered as a weekly infusion. Eligibility requires biochemical and/or genetic confirmation of Morquio A. The manufacturer is BioMarin. Dosing is typically 2 mg/kg IV once weekly. The product requires refrigerated storage (2-8 degrees C) and reconstitution before infusion. Monitoring includes urinary GAG levels, pulmonary function, endurance (6-minute walk), cardiac parameters, infusion-reaction surveillance, and antibody response. Your specialist will confirm Morquio A diagnosis and coordinate the infusion plan.

Is Vimizim legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, administered via the administering hospital's importing pharmacy and the SFDA Drug Directorate. The Saudi Arabia has a mature named-patient mechanism that supports cross-border access to rare-disease enzyme-replacement therapies.

The framework rests on four anchors: (a) the medicine is approved by a recognised reference authority (FDA qualifies), (b) no clinically equivalent locally registered alternative is suitable for the patient, (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 Vimizim 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 Vimizim is clinical, based on Morquio A confirmation and organ-system status. Your specialist documents the rationale.
2. **Infusion-facility identification.** A Saudi Arabiaian tertiary hospital or infusion centre equipped for weekly enzyme-replacement infusions accepts the case.
3. **SFDA named-patient application.** Your physician or the hospital's importing pharmacy files an application with SFDA 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.** Vimizim 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, reflecting the weekly cadence.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming Morquio A diagnosis and Vimizim as the indicated therapy
- Verification of their Saudi Arabiaian medical licence (JMC / MOH)
- A current prescription naming the product, dose (mg/kg), and weekly 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 SFDA reviewers expect to see for named-patient import of cold-chain rare-disease enzyme-replacement therapies.

Costs and timing

Vimizim's US cash-pay drug-only reference price is weight-dependent. A typical paediatric annual cost sits in an indicative 2026 drug-only range (delivered quote issued at intake) of roughly USD 400,000-650,000 for ongoing weekly infusions (adult costs scale with weight). Logistics, SFDA 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 SFDA application is submitted. Subsequent cycles are scheduled to match the 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.

Reserve Meds's role

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Vimizim 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 SFDA 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 weekly-infusion cycle.

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 metabolic specialist and the infusion facility.

Frequently asked

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

Why weekly infusions? Vimizim's pharmacokinetics require weekly dosing. Infusions typically last several hours; your specialist will discuss home-infusion versus hospital-infusion options.

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.

Will private insurance or MOH coverage apply? Cash-pay is the default. Some Saudi Arabiaian 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.

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