# Vimizim access in Jordan: the JFDA named-patient pathway

How Jordanian and regional patients pursue elosulfase alfa, an enzyme replacement therapy for Morquio A syndrome, a rare lysosomal storage disorder, when conventional management has reached its limit.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team. This page combines the Jordan country research module with the Vimizim drug module to describe the path families actually walk.*

## Quick orientation

Vimizim (elosulfase alfa) is a recombinant human N-acetylgalactosamine-6-sulfatase enzyme replacement therapy manufactured by BioMarin Pharmaceutical. The drug was approved by the US Food and Drug Administration in February 2014 for the treatment of Morquio A syndrome, also known as mucopolysaccharidosis type IVA (MPS IVA), a rare autosomal recessive lysosomal storage disorder caused by deficiency of the GALNS enzyme. The deficiency results in accumulation of keratan sulfate and chondroitin-6-sulfate glycosaminoglycans, particularly affecting skeletal development, cardiac function, respiratory function, and endurance. Vimizim is administered as a weekly intravenous infusion of 2 mg/kg over approximately 3.5 to 4.5 hours, with pre-medication for infusion reactions. The treatment is lifelong; this is enzyme replacement, not a cure. Reserved for you.

## Why this drug is hard to source in Jordan

Morquio A syndrome is a rare disease. The estimated global incidence is approximately 1 per 200,000 to 300,000 live births, although consanguinity rates in parts of the Middle East and North Africa can increase the regional incidence above the global average. Jordan, with its higher consanguinity rates and its role as a regional referral center for patients from Iraq, Palestine, Syria, Yemen, and other countries with similar genetic backgrounds, sees Morquio A cases at a meaningful clinical volume given the rare-disease classification.

Vimizim is not registered in Jordan and has limited registration footprint across the MENA region. The patient population is small, the manufacturer (BioMarin) operates a focused commercial footprint concentrated in major markets, and named-patient import is the standard global pathway for the molecule in markets where it is not registered. The JFDA

named-patient permit closes the gap, allowing the treating metabolic disease specialist or pediatric geneticist to import the drug in the patient's name for weekly infusion at a JFDA-licensed dispensing institution.

For Jordanian-resident pediatric patients with a confirmed Morquio A diagnosis, the pathway typically routes through the academic teaching hospital network. For regional patients who have come to Jordan for diagnostic work-up or specialty care, the pathway can route through the receiving Jordanian institution for the course of care in Jordan.

## The JFDA named-patient pathway

The Jordan Food and Drug Administration, headquartered in Amman, administers the personal-use and named-patient import permit under the Drug Directorate. The pathway allows hospitals, licensed pharmaceutical importers, and retail pharmacies operating under physician prescription to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (US FDA, EMA, MHRA, Health Canada, TGA, PMDA) and a locally registered alternative is not suitable or available.

For a Vimizim case, the standard application set applies, with three additions specific to enzyme replacement therapy for a rare lysosomal storage disorder. First, the clinical justification letter documents the Morquio A diagnosis with the GALNS gene sequencing result or the enzyme assay result confirming N-acetylgalactosamine-6-sulfatase deficiency. Genetic confirmation is the diagnostic standard; enzyme assay on leukocytes or cultured fibroblasts is the supporting biochemical evidence. Second, the application typically captures the patient's baseline functional assessment, including the 6-minute walk test result, the 3-minute stair climb test result where assessed, pulmonary function testing where age-appropriate, and the cardiac evaluation. Third, the dose calculation is documented based on the patient's weight (2 mg/kg weekly) and the planned ordering quantity covers the expected weeks of supply with cold-chain margin.

A complete JFDA application typically includes the clinical justification letter from the treating metabolic disease specialist or pediatric geneticist, the physician JPA membership and MOH registration verification, the patient identifier, full product details (brand name Vimizim, generic name elosulfase alfa, manufacturer BioMarin, 5 mg/5 mL single-use vial, pack size, quantity, intended duration), the destination dispensing facility name and JFDA pharmaceutical establishment license number, the Morquio A diagnostic documentation, the dose calculation, and a cold-chain plan covering 2 to 8 degrees Celsius transport. Vimizim is a refrigerated biologic; the cold-chain documentation is integral. Approval timelines run 7 to 21 calendar days from a complete submission. First-of-kind submissions for a previously-unregistered rare-disease ERT may run longer, in the 4 to 6 week range, while the JFDA performs additional review.

## Real costs in JOD and USD

The US wholesale acquisition cost for Vimizim is approximately USD 380,000 to 410,000 per patient per year at the standard weekly dose of 2 mg/kg, for an average pediatric or young-adult patient weight. The annual cost scales with the patient weight; a heavier patient consumes more drug. In JOD at the 0.71 peg, the annual cost is approximately JOD 270,000 to 291,000.

This is a treatment-for-life drug, not a finite course. The cumulative cost over a multi-decade treatment horizon is substantial. Reserve Meds cannot reduce the manufacturer's wholesale acquisition cost; we can quote the per-shipment cost transparently and we can structure the supply cadence to align with the patient's clinical schedule (typically a 4 to 12 week shipment cadence depending on storage capacity at the dispensing institution).

International logistics for a cold-chain biologic into Jordan typically runs USD 1,200 to 2,500 (approximately JOD 850 to 1,775) per shipment depending on shipment size, dry-ice requirement, and urgency. JFDA permit fees and Jordan Customs handling are nominal relative to the drug cost. Regulatory documentation handling and the Reserve Meds concierge fee are itemised separately on every firm quote.

On the insurance side, RMS and MOH schemes assess rare-disease ERT case by case. RMS has historically supported rare-disease ERT for military-family beneficiaries through individual case authorisation. The MOH civil-servant scheme similarly assesses case by case. KHCC does not typically take pediatric metabolic cases, but the academic teaching hospitals (JUH, KAUH) and the private pediatric specialty services do. Private insurers (MetLife, Generali, Arab Orient, Jordan Insurance, Mediterranean and Gulf) assess rare-disease ERT individually and most require pre-authorisation and documentation of the rare-disease diagnostic confirmation. Cash-pay is a structurally difficult default for a treatment-for-life ERT of this annual cost; most cases route through a combination of insurance, government support, manufacturer patient assistance where applicable, and family contribution. Reserve Meds supplies the documentation set that lets your insurer assess the case. We do not promise coverage from any insurer.

## Timing, what to expect

The JFDA permit itself processes in approximately 7 to 21 calendar days from a complete submission. The full timeline from the first physician contact to the patient receiving the first dose is typically 4 to 8 weeks for a Vimizim case, broken down approximately as follows. Initial documentation kit delivery to the physician runs 24 to 48 hours from waitlist confirmation. The treating physician clinical justification letter and Morquio A diagnostic documentation assembly typically takes 1 to 2 weeks, longer if genetic confirmation testing is still in progress. The JFDA application filing and approval window runs 7 to 21 calendar

days for routine submissions; first-of-kind ERT submissions may run 4 to 6 weeks. US-side sourcing, run in parallel, takes 5 to 10 business days. Cold-chain shipment and customs clearance at Queen Alia International Airport typically takes 2 to 4 business days post-shipment.

Once therapy begins, the dose schedule is 2 mg/kg intravenously once weekly, infused over approximately 3.5 to 4.5 hours, with pre-medication for infusion reactions (antihistamine, antipyretic, with corticosteroid in some cases). The treatment is lifelong. Most patients show measurable improvement in the 6-minute walk test and other functional endpoints within the first 24 to 48 weeks of therapy, with continued slower gains over years.

## What your physician needs

The clinical justification letter for a Vimizim JFDA submission is the cornerstone of the application. The treating physician letter typically addresses the Morquio A diagnosis (with GALNS gene sequencing result or enzyme assay result), the baseline functional assessment (6-minute walk test, 3-minute stair climb test, pulmonary function testing where age-appropriate, cardiac evaluation, skeletal imaging), the rationale for ERT initiation now, the dose calculation based on patient weight, the planned infusion setting, and the monitoring plan for known class effects (infusion reactions, anti-drug antibody development, ongoing functional reassessment).

The treating physician JPA membership and MOH registration must be in active standing. The destination dispensing facility must hold a JFDA pharmaceutical establishment license. The Morquio A diagnostic confirmation must be documented from a recognised molecular genetics or biochemical genetics laboratory. The patient identifier is included on the application. For pediatric cases, the parent or legal guardian informed consent for lifelong ERT is part of the dispensing record.

## King Hussein Cancer Center and the Jordan specialty-dispensing network

Vimizim for Morquio A is not a King Hussein Cancer Center case; KHCC's mandate is oncology and hematology, not metabolic disease. The natural dispensing institutions for a pediatric metabolic ERT in Jordan are the academic teaching hospitals.

Jordan University Hospital in Amman, with its established pediatrics service line and its academic affiliation with the University of Jordan Faculty of Medicine, is the natural Amman-area dispensing institution. JUH operates an in-house import pharmacy, holds JFDA pharmaceutical establishment licensing, and has experience with rare-disease ERT cases. King Abdullah University Hospital in Irbid, similarly, is the natural northern-Jordan dispensing institution with its academic affiliation to the Jordan University of Science and

Technology. For private-sector cases, Istishari Hospital and Specialty Hospital both have pediatric service lines and can serve as the dispensing institution when paired with an Amman-based specialty pharmaceutical importer.

For pediatric metabolic disease cases, the in-country specialist network is small. The treating physician is typically a pediatric geneticist or pediatric metabolic disease specialist credentialed in Jordan. Reserve Meds coordinates US-side sourcing and shipment once the treating physician is identified and the JFDA pathway is in motion; we do not select the dispensing institution on the patient behalf, but we can connect the family physician with the JUH or KAUH metabolic disease team where introduction is helpful.

## Pharmacovigilance and cold-chain

Vimizim is a refrigerated biologic. The single-use 5 mg/5 mL vial is stored at 2 to 8 degrees Celsius (refrigerated, not frozen) and protected from light. The cold-chain documentation captures temperature trace from US release through Jordanian dispensing. Reserve Meds supplies the chain-of-custody packet (release documentation, shipping temperature trace, US customs filings) to the Jordanian importer and to the hospital pharmacy on receipt. Excursions outside the 2 to 8 degree window are evaluated against the manufacturer specified excursion limits and the affected vials are quarantined where the excursion exceeds the limit.

Jordan operates a national pharmacovigilance system administered by the JFDA Drug Directorate, and is a member of the WHO Programme for International Drug Monitoring through the Uppsala Monitoring Centre. The treating physician and the dispensing facility share the duty to report adverse drug reactions through the JFDA portal at jfda.jo. The Vimizim safety profile includes infusion reactions (common, generally manageable with pre-medication and infusion rate adjustment) and anaphylaxis (rare but reported). Anti-drug antibody development is monitored over time. Serious adverse reactions are reported within 15 calendar days; other significant adverse events fall within 30-day or 90-day windows depending on severity. Reserve Meds does not file adverse-event reports on the physician behalf.

## Common questions about Vimizim in Jordan

**Is genetic testing for Morquio A available in Jordan?** Yes, but capacity is limited. JUH, KAUH, and a small number of Jordanian commercial reference laboratories offer GALNS gene sequencing. For many cases, the genetic testing is referred to a regional or international laboratory. Reserve Meds does not provide diagnostic testing; the JFDA application requires the diagnostic documentation to be in hand.

**Will RMS, MOH, or private insurers cover lifelong ERT at this cost?** Coverage is case by case. RMS has historically supported rare-disease ERT for military-family beneficiaries through individual case authorisation. MOH similarly assesses case by case. Private insurers assess individually with rare-disease confirmation as the entry criterion. Manufacturer patient assistance programmes may apply in some markets. We supply the documentation set that lets your insurer or assistance programme assess the case.

**Can my regional patient (Iraq, Palestine, Syria) receive Vimizim through Jordan?** Where the patient is under the care of a Jordanian metabolic disease specialist and the infusion is delivered at a JFDA-licensed Jordanian institution, the named-patient permit can be filed in the patient name with the country-of-residence passport as the identifier. The supply cadence accommodates a Jordan-based infusion schedule. Continuation after the patient returns home routes through the home-country regulatory pathway.

**Are infusion reactions a problem?** Infusion reactions are common with Vimizim, especially in the first months of therapy. Pre-medication with antihistamine and antipyretic is standard, and the infusion rate is adjusted on the treating physician judgment. Most reactions are manageable in the infusion setting. Anaphylaxis is rare but the infusion setting is prepared for it.

**Is Vimizim a controlled substance?** No. Vimizim is not a DEA scheduled substance. The Anti-Narcotics Department coordination does not apply.

## Where Reserve Meds fits in Vimizim cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating metabolic disease specialist, the JFDA, the dispensing pharmacy, or the receiving institution. For a Vimizim case, the engagement is lifelong rather than a single course; our work is the recurring supply cadence over years, the chain-of-custody documentation on each shipment, and a single named coordinator across the relationship. Reserve Meds coordinates US-side sourcing, cold-chain shipment to the Jordanian importer or hospital pharmacy of record, and supply continuity. The clinical decisions, the JFDA filing, and the infusion delivery all sit with your Jordanian physician and the dispensing institution. Reserved for you.

## Next step

If a treating metabolic disease specialist or pediatric geneticist in Jordan is initiating Vimizim for a patient with confirmed Morquio A syndrome, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

*Reserved for you.*

## Related

- Vimizim clinical resource
- Vimizim in Saudi Arabia
- Vimizim in the UAE
- Jordan country page
- Morquio A syndrome condition page

## Sources


1. FDA approval, Vimizim (elosulfase alfa), BioMarin Pharmaceutical, BLA approval February 2014 for Morquio A syndrome (mucopolysaccharidosis type IVA).
2. Jordan Food and Drug Administration, jfda.jo, Drug Directorate framework for personal-use and named-patient import permits; Law No. 41 of 2008.
3. Central Bank of Jordan, fixed exchange rate framework, JOD-USD peg at approximately 0.71 JOD per USD since 1995.
4. Morquio A epidemiology and consanguinity-region variation literature; manufacturer prescribing information for elosulfase alfa.



**Review and oversight.** Content on this page is reviewed by the Reserve Meds clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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