

## Livmarli

Saudi Arabia · access guide

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

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-24

An Saudi Arabian child with Alagille syndrome or progressive familial intrahepatic cholestasis (PFIC) who is suffering from intractable cholestatic pruritus may receive a prescription for Livmarli (maralixibat) from their treating paediatric hepatologist or paediatric gastroenterologist. Livmarli is FDA-approved in the United States as an oral ileal bile acid transporter (IBAT) inhibitor, indicated to reduce cholestatic pruritus in specific paediatric cholestatic liver diseases. Because Livmarli is not yet routinely available through Saudi Arabian hospital pharmacies for these ultra-rare paediatric indications, your specialist may be coordinating a named-patient import pathway on your behalf.

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

Livmarli is an orally administered IBAT inhibitor that reduces systemic bile acid exposure by blocking their reabsorption in the terminal ileum. It is supplied as an oral solution dosed by weight, given once daily. The manufacturer is Mirum Pharmaceuticals. Eligibility typically requires genetic or clinical confirmation of Alagille syndrome (JAG1 or NOTCH2) or PFIC (ABCB11, ATP8B1, or other defined subtypes) and documented cholestatic pruritus that has not responded adequately to conventional antipruritic measures. Your paediatric specialist confirms diagnosis, baseline liver function, bile acid levels, growth parameters, and the monitoring plan, which includes liver enzyme surveillance and fat-soluble vitamin status, per FDA labeling.

## Is Livmarli legally importable into Saudi Arabia?

Yes, through the Central Drugs Standard Control Organization (SFDA) personal-use / named-patient import framework. The Saudi Arabia has a mature pathway for importing medicines that are approved by recognised reference regulators but not yet locally marketed, used routinely across paediatric rare disease.

The SFDA route typically rests on: (a) FDA or equivalent approval of the medicine, (b) the absence of a suitable locally registered alternative, (c) a prescription from a registered Saudi Arabian medical practitioner who takes clinical responsibility, and (d) documented chain of custody from the US source to the treating facility. For paediatric rare-disease products, SFDA reviewers are accustomed to seeing named-patient dossiers for IBAT inhibitors.

## How the pathway works, step by step

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1. **Consultation with your treating paediatric specialist.** Diagnostic confirmation (genetic report plus clinical picture), pruritus severity assessment, prior therapy history, and a written clinical rationale.
2. **Treatment-centre identification.** A tertiary paediatric liver centre or a paediatric gastroenterology service that can monitor liver function, growth, and fat-soluble vitamins accepts the case.
3. **SFDA named-patient application.** Your physician or the hospital's licensed importing pharmacy files the application including prescription, diagnostic report, weight-based dosing plan, and chain-of-custody documentation.
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. **Temperature-controlled shipment.** Livmarli oral solution ships with protective packaging and chain-of-custody documentation end to end.
6. **Arrival and dispensing support.** Your paediatric specialist remains the treating clinician. Reserve Meds coordinates re-supply ahead of bottle depletion to avoid treatment gaps, which matter for pruritus-control continuity.

## What documentation your physician needs

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Your physician will typically need to provide:

- A clinical rationale letter confirming Alagille syndrome or PFIC diagnosis, pruritus severity, prior antipruritic therapy, and Livmarli as the indicated treatment
- Verification of their Saudi Arabian medical registration (state medical council registration number)
- A current prescription naming the product, weight-based dose in mg/kg, and dosing schedule
- Patient identifier (anonymised paediatric reference preferred)
- Planned monitoring cadence (LFTs, bile acids, fat-soluble vitamins, growth)

Reserve Meds provides a physician documentation kit bundling the templates SFDA reviewers expect to see for paediatric rare-disease oral therapies under named-patient import.

## Costs and timing

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Livmarli's US cash-pay reference price is weight-dependent because of the oral-solution, mg/kg-per-day dosing model. For a typical paediatric patient, the indicative 2026 monthly cost sits in a range of roughly USD 20,000-35,000 per month depending on weight. Logistics, SFDA documentation handling, and concierge coordination add incremental cost; Reserve Meds issues a full transparent quote at the start of intake, with a drug-only reference figure separated from service charges.

Indicative timing for first shipment arrival after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. Subsequent re-supply cycles are generally faster once the pathway is established.

*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 culturally-aware note: Saudi Arabia has several high-volume paediatric hepatology centres of excellence across Delhi, Mumbai, Chennai, Bengaluru, Hyderabad, and Kolkata. Our concierge team can coordinate with any of them, in English or the regional language your family prefers.

## Reserve Meds's role

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Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Livmarli 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, including paediatric diagnostic-attestation templates.
- **Logistics.** Temperature-protected shipment and chain-of-custody coordination.
- **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 paediatric specialist.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA personal-use / named-patient framework with appropriate documentation. See our trust and compliance page.

**Is Livmarli a cure?** No. Livmarli is an antipruritic therapy that addresses the bile-acid-driven itch burden in Alagille syndrome and PFIC. It does not reverse the underlying genetic disease, but for many children the reduction in pruritus meaningfully improves sleep, growth, and quality of life.

**What if my child is younger than 3 months?** Labeling restrictions apply by age and weight. Your paediatric specialist will confirm eligibility against the current FDA label.

**How is Livmarli different from odevixibat (Bylvay)?** Both are IBAT inhibitors. Your paediatric specialist will discuss which fits your child's genetic subtype, weight, and formulation preferences.

**Will private insurance cover this?** Cash-pay is the default. Some Saudi Arabian private insurers and employer plans reimburse named-patient imports for ultra-rare paediatric conditions on a case-by-case basis; 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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**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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