Mepsevii

Saudi Arabia · access guide

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

By Reserve Meds, Clinical and regulatory team. Last reviewed 2026-05-13.

A Saudi Arabia patient with mucopolysaccharidosis VII (MPS VII, Sly syndrome) may receive a prescription for Mepsevii (vestronidase alfa-vjbk) from their treating metabolic geneticist. Mepsevii is FDA-approved in the United States and manufactured by Ultragenyx Pharmaceutical. It is a recombinant beta-glucuronidase enzyme replacement therapy administered by intravenous infusion. Local availability of Mepsevii in Saudi Arabia can be inconsistent: the drug may not be on every specialty pharmacy's standing formulary, the specific indication may not match what is locally registered, or the strength required may be back-ordered. When that happens, a named-patient import pathway through SFDA remains a legitimate route for the patient whose physician has already prescribed the drug.

This guide explains the pathway, the documentation your physician needs, typical costs and indicative timing, and where Reserve Meds fits in.

The clinical situation

Mepsevii is a recombinant beta-glucuronidase enzyme replacement therapy. Mechanism: a recombinant form of human beta-glucuronidase that catalyses the hydrolysis of terminal glucuronic acid residues from glycosaminoglycans. Dosing: 4 mg/kg by intravenous infusion every two weeks, with pre-infusion antihistamine and antipyretic premedication, per FDA labeling. Baseline workup per FDA labeling includes urinary GAG baseline, cardiac and pulmonary evaluation, airway assessment, hepatosplenomegaly assessment, and infusion-reaction risk screening. The FDA boxed warning covers anaphylaxis. Other important warnings include anaphylaxis and severe allergic reactions, infusion-associated reactions, and patients with significant skeletal or airway disease may be at higher risk. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Mepsevii legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated with the treating facility's pharmacy. The Saudi Arabia has an established pathway for specialty medicines approved by reference authorities (US FDA, EMA, MHRA) but not stocked or registered for the specific indication locally.

The SFDA named-patient route allows a Saudi Arabia-licensed physician to request import of a medicine when: (a) the medicine is approved by a recognised reference authority, (b) no clinically equivalent locally registered alternative is suitable for the patient's indication and history, (c) the treating physician takes clinical responsibility for use, and (d) chain of custody is documented from the US source to the administering facility. Applications are typically filed through the dispensing institution's import pharmacy on the physician's behalf, with approval issued on a per-patient, per-cycle quantity basis.

How the pathway works, step by step

1. **Consultation with your treating specialist.** The prescribing decision is clinical. Your specialist documents the indication, prior therapies where relevant, and rationale for Mepsevii.
2. **Baseline screening.** Urinary GAG baseline, cardiac and pulmonary evaluation, airway assessment, hepatosplenomegaly assessment, and infusion-reaction risk screening are confirmed and documented.
3. **SFDA named-patient application.** Your specialist or the facility's import pharmacy files the application with clinical rationale, patient reference, product strength, quantity requested, and chain-of-custody plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure product from Ultragenyx Pharmaceutical's authorised distribution under DSCSA chain-of-custody.
5. **Cold-chain shipment.** Mepsevii requires refrigerated transport at 2 to 8 degrees Celsius. Shipments include temperature-monitored packaging with continuous loggers and tamper-evident seals.
6. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your specialist initiates therapy.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming diagnosis, prior therapies where relevant, and Mepsevii as the indicated next step
- Verification of their Saudi Arabia medical licence
- A patient identifier, anonymised reference where privacy is preferred
- Documented pre-treatment screening consistent with FDA labeling (see above)
- The planned dosing regimen (4 mg/kg by intravenous infusion every two weeks, with pre-infusion antihistamine and antipyretic premedication, per FDA labeling)
- A monitoring plan covering GAG baselines, airway and skeletal imaging summary, and pre-medication protocol

Reserve Meds provides a physician documentation kit tailored for MPS enzyme replacement therapy therapies, including the templates SFDA reviewers commonly request.

Typical costs and indicative timing

Reserve Meds gives you a drug-only reference range plus a transparent delivered quote at intake. As an illustrative composite case, the US cash-pay reference range for a typical month of every-2-week infusions (weight-dependent) of Mepsevii sits in an indicative 2026 band of approximately USD 60,000 to 85,000. International logistics, SFDA documentation handling, cold-chain shipping, and concierge coordination add incremental cost. The delivered quote we issue at intake shows each line separately.

Indicative timing for first dose after cohort intake opens is approximately 4 to 8 weeks from the moment a complete application is submitted, assuming the documentation package is clean on first pass. Refills ship on a rolling cadence aligned to the dosing schedule.

Service availability is limited to our first cohort. All timelines are indicative, not guarantees.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Mepsevii specifically, we provide:

- **Sourcing.** Through our US-licensed specialty wholesale partner, operating under DSCSA chain-of-custody from manufacturer to export.
- **Documentation.** Regulatory package tailored for your physician and for SFDA review, including MPS enzyme replacement therapy class templates.
- **Cold-chain logistics.** Temperature-monitored, internationally tracked shipment to your named dispensing facility with continuous temperature loggers.
- **Concierge case lead.** A named point of contact for your family and your physician across the full case arc.

We are a coordinator. We are not the prescriber, not a pharmacy, and not a dispensing facility. All clinical decisions remain with your treating specialist, and dispensing sits with the licensed Saudi Arabia pharmacy of record. Reserve Meds operates on cash-pay only and does not bill insurance.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the SFDA named-patient and personal-use framework with appropriate documentation, clinical rationale, and a licensed dispensing facility. The pathway is routinely used across oncology, rare disease, and immunology at Saudi Arabia tertiary centers.

What about the boxed warning? The FDA boxed warning on Mepsevii covers anaphylaxis. Your specialist performs the risk-benefit assessment, schedules monitoring, and counsels the patient per labeling. Reserve Meds does not make that clinical judgement, your physician does.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabia private insurers and CCHI-aligned plans reimburse named-patient imports on a case-by-case basis when the documentation package is strong. We supply documentation for your submission but do not process insurance claims.

How does cold-chain affect timing? Mepsevii ships refrigerated. We use validated packaging with continuous temperature monitoring, and arrival temperature data is logged on every shipment.

What if my physician has not filed a named-patient request before? Named-patient import is an institutional process most major Saudi Arabia tertiary centers (King Faisal Specialist Hospital and Research Centre, King Abdulaziz Medical City, and KFSHRC Jeddah) have encountered. Our documentation kit is written for first-time applicants and tracks what SFDA reviewers commonly ask for.

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.

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