Filspari

Saudi Arabia · access guide

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

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

An Saudi Arabia patient with primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression, to reduce proteinuria may receive a prescription for Filspari (sparsentan) from their treating nephrologist. Filspari is FDA-approved in the United States and manufactured by Travere Therapeutics. It is a dual endothelin and angiotensin II receptor antagonist administered by oral tablet. Local availability of Filspari 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

Filspari is a dual endothelin and angiotensin II receptor antagonist. Mechanism: a non-immunosuppressive selective dual antagonist of the endothelin type A receptor and the angiotensin II type 1 receptor. Dosing: 400 mg orally once daily after a starting dose of 200 mg for 14 days, per FDA labeling, dispensed under a US REMS program. Baseline workup per FDA labeling includes liver function tests including ALT, AST, and total bilirubin; urinary protein-creatinine ratio; estimated GFR; and pregnancy testing in females of reproductive potential. The FDA boxed warning covers hepatotoxicity and embryo-fetal toxicity, with US REMS-required liver function monitoring. Other important warnings include hepatotoxicity requiring monthly liver function monitoring for the first 12 months and embryo-fetal toxicity; dispensed only under a REMS program in the US for these risks; hypotension, acute kidney injury, hyperkalemia, and fluid retention. Your nephrologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Filspari legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient and personal-use import framework, coordinated through a Saudi Arabia-licensed 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 an 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 nephrologist.** The prescribing decision is clinical. Your nephrologist documents the indication, prior therapies where relevant, and rationale for Filspari.
2. **Baseline screening.** Liver function tests including ALT, AST, and total bilirubin; urinary protein-creatinine ratio; estimated GFR; and pregnancy testing in females of reproductive potential are confirmed and documented.
3. **SFDA named-patient application.** Your nephrologist 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 Travere Therapeutics's authorised distribution under DSCSA chain-of-custody.
5. **Arrival and first dose.** The dispensing pharmacy releases product against the physician's prescription, and your nephrologist 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 Filspari 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 (400 mg orally once daily after a starting dose of 200 mg for 14 days, per FDA labeling, dispensed under a US REMS program)
- A monitoring plan covering REMS-aligned monthly LFT monitoring plan, pregnancy testing protocol, and proteinuria and eGFR baselines

Reserve Meds provides a physician documentation kit tailored for IgAN oral 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 daily dosing of Filspari sits in an indicative 2026 band of approximately USD 15,000 to 20,000. International logistics, SFDA documentation handling, 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 2 to 5 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 Filspari 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 IgAN oral therapy class templates.
- **Logistics.** Internationally tracked shipment to your named dispensing facility with tamper-evident packaging.
- **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 nephrologist, 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 Filspari covers hepatotoxicity and embryo-fetal toxicity, with US REMS-required liver function monitoring. Your nephrologist 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 (Daman, AXA, Mednet-administered 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.

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 (Cleveland Clinic Abu Dhabi, Sheikh Shakhbout Medical City, American Hospital Dubai, and Mediclinic City Hospital) 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.

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