Opsynvi

Saudi Arabia · access guide

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

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

An Saudi Arabian adult with pulmonary arterial hypertension (PAH, WHO Group 1) may receive a prescription for Opsynvi (a fixed-dose combination of macitentan and tadalafil) from their treating pulmonologist or PAH specialist. Opsynvi is FDA-approved in the United States as a single once-daily oral tablet combining an endothelin-receptor antagonist (macitentan) with a PDE-5 inhibitor (tadalafil), intended to simplify dual-pathway PAH therapy for appropriate patients. Because Opsynvi is not yet routinely stocked in Saudi Arabian hospital pharmacies, 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

Opsynvi is a once-daily oral fixed-dose combination providing macitentan 10 mg with tadalafil 40 mg. The manufacturer is Johnson & Johnson (Janssen/Actelion). Eligibility rests on confirmed WHO Group 1 PAH (typically supported by right heart catheterisation) where dual oral therapy with an ERA and a PDE-5 inhibitor is the clinical plan. The label provides a pathway for patients starting de novo on dual therapy and for patients consolidating from separate macitentan and tadalafil tablets onto a single pill. Your specialist confirms diagnosis, haemodynamics, risk stratification, drug interactions (including nitrates, which are contraindicated with tadalafil), and the monitoring plan, which includes liver function for the ERA component and standard PAH follow-up, per FDA labeling.

Is Opsynvi 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 for specialty cardiopulmonary products.

The SFDA route typically rests on: (a) FDA or equivalent approval of the medicine, (b) the absence of a suitable locally registered alternative (in this case a single-pill dual-pathway PAH combination), (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.

How the pathway works, step by step

1. **Consultation with your treating PAH specialist.** Confirmation of WHO Group 1 PAH, right heart catheterisation findings, dual-therapy indication, drug-interaction review, and a written clinical rationale.
2. **Treatment-centre identification.** A tertiary pulmonology or cardiology service with PAH expertise and LFT monitoring capability accepts the case.
3. **SFDA named-patient application.** Your physician or the hospital's licensed importing pharmacy files the application including prescription, diagnostic documentation, 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. **Stable shipment.** Opsynvi is an oral tablet with standard storage requirements and ships with chain-of-custody documentation end to end.
6. **Arrival and initiation.** Your specialist starts therapy at one tablet once daily and arranges follow-up LFTs and PAH status assessments. Reserve Meds coordinates re-supply ahead of bottle depletion.

What documentation your physician needs

Your physician will typically need to provide:

- A clinical rationale letter confirming WHO Group 1 PAH, right heart catheterisation findings, dual-therapy rationale, and Opsynvi as the indicated fixed-dose combination
- Verification of their Saudi Arabian medical registration (state medical council registration number)
- A current prescription naming the product, once-daily dosing, and the planned schedule
- Patient identifier (anonymised reference preferred)
- Planned monitoring cadence (LFTs, haemoglobin, PAH status)

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

Costs and timing

Opsynvi's US cash-pay reference price for a 30-day supply sits in an indicative 2026 range of roughly USD 13,000-16,000. 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 PAH 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

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Opsynvi 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 PAH-diagnostic attestation templates.
- **Logistics.** Shipment coordination and chain-of-custody.
- **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 PAH specialist.

Frequently asked

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.

Why a fixed-dose combination instead of separate pills? Single-pill combinations reduce pill burden and can improve adherence in chronic therapies like PAH. The choice between separate and combined tablets is a clinical decision based on your specialist's preference and your individual case.

Are there contraindications I should know about? Yes, concurrent nitrates (for angina) are contraindicated with tadalafil and therefore with Opsynvi. Your specialist reviews the full interaction list before prescribing.

Do I still need monitoring if the components are familiar? Yes. ERA-class agents carry liver-function monitoring requirements, and PAH follow-up continues on the standard cadence your specialist sets.

Will private insurance cover this? Cash-pay is the default. Some Saudi Arabian private insurers and employer plans reimburse named-patient PAH imports 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.

reservemeds.com · hello@reservemeds.com