

Vyndaqel

Saudi Arabia · access guide

How to access Vyndaqel 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 cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalisation may receive a prescription for Vyndaqel (tafamidis meglumine) from their treating cardiologist with amyloidosis experience. Vyndaqel is FDA-approved in the United States and manufactured by Pfizer. It is a transthyretin stabiliser administered by oral capsule. Local availability of Vyndaqel 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 MoPH 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

Vyndaqel is a transthyretin stabiliser. Mechanism: a small-molecule stabiliser that binds the thyroxine-binding sites of transthyretin and prevents tetramer dissociation. Dosing: 80 mg (four 20 mg capsules) once daily by mouth, per FDA labeling; tafamidis free acid (Vyndamax) is an alternative formulation at 61 mg once daily. Baseline workup per FDA labeling includes cardiac evaluation including echocardiogram and cardiac biomarkers, neurologic assessment for concurrent polyneuropathy, and liver function. Other important warnings include generally well-tolerated; common adverse events include diarrhea and urinary tract infection in some studies. Your specialist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Vyndaqel legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Ministry of Public Health (MoPH) 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 MoPH 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 Vyndaqel.
2. **Baseline screening.** Cardiac evaluation including echocardiogram and cardiac biomarkers, neurologic assessment for concurrent polyneuropathy, and liver function are confirmed and documented.
3. **MoPH 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 Pfizer'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 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 Vyndaqel 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 (80 mg (four 20 mg capsules) once daily by mouth, per FDA labeling; tafamidis free acid (Vyndamax) is an alternative formulation at 61 mg once daily)
- A monitoring plan covering echocardiogram and cardiac biomarker baseline, and storage protocol

Reserve Meds provides a physician documentation kit tailored for ATTR-CM oral therapy therapies, including the templates MoPH 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 Vyndaqel sits in an indicative 2026 band of approximately USD 18,000 to 24,000. International logistics, MoPH 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 Vyndaqel 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 MoPH review, including ATTR-CM 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 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 MoPH 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.

Will my private health insurance cover this? Cash-pay is the default posture. Some Saudi Arabia private insurers 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 (Hamad Medical Corporation, the National Center for Cancer Care and Research, and Sidra Medicine) have encountered. Our documentation kit is written for first-time applicants and tracks what MoPH 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.

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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