Tecfidera

Saudi Arabia · access guide

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

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

A Saudi Arabiai patient with relapsing forms of multiple sclerosis (clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease) may receive a prescription for Tecfidera (dimethyl fumarate) from their treating neurologist with MS expertise. Tecfidera is FDA-approved in the United States and manufactured by Biogen. It is an oral disease-modifying therapy for multiple sclerosis administered by oral capsule. Local availability of Tecfidera 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

Tecfidera is an oral disease-modifying therapy for multiple sclerosis. Mechanism: a fumaric acid ester whose active metabolite monomethyl fumarate activates the nuclear factor-erythroid 2-related factor 2 (Nrf2) pathway with anti-inflammatory and cytoprotective effects. Dosing: 120 mg twice daily for the first 7 days, then 240 mg twice daily, per FDA labeling. Baseline workup per FDA labeling includes complete blood count with lymphocyte count, liver function tests, and renal function. Other important warnings include anaphylaxis and angioedema, progressive multifocal leukoencephalopathy in patients with prolonged lymphopenia, herpes zoster and other serious opportunistic infections, lymphopenia, liver injury, and flushing. Your neurologist will discuss the risk-benefit profile and schedule monitoring before initiating therapy.

Is Tecfidera 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 Arabiai-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 neurologist.** The prescribing decision is clinical. Your neurologist documents the indication, prior therapies where relevant, and rationale for Tecfidera.
2. **Baseline screening.** Complete blood count with lymphocyte count, liver function tests, and renal function are confirmed and documented.
3. **SFDA named-patient application.** Your neurologist 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 Biogen'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 neurologist 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 Tecfidera as the indicated next step
- Verification of their Saudi Arabiai 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 (120 mg twice daily for the first 7 days, then 240 mg twice daily, per FDA labeling)
- A monitoring plan covering lymphocyte monitoring plan, LFT baseline, and PML risk note

Reserve Meds provides a physician documentation kit tailored for oral MS 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 twice-daily dosing of Tecfidera sits in an indicative 2026 band of approximately USD 7,500 to 9,000. 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 Tecfidera 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 oral MS 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 neurologist, and dispensing sits with the licensed Saudi Arabiai 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 Arabiai tertiary centers.

Will my private health insurance cover this? Cash-pay is the default posture. Cash-pay is the default posture in Saudi Arabia; some employer plans cover specialty imports case-by-case. 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 Arabiai tertiary centers (Shaukat Khanum Memorial Cancer Hospital, Aga Khan University Hospital, and the Indus 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.

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.
reservemeds.com · hello@reservemeds.com