

## Mayzent

Saudi Arabia · access guide

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

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabia patient with relapsing forms of multiple sclerosis, especially active secondary-progressive MS, may receive a prescription for Mayzent (siponimod) from their treating neurologist. Mayzent is FDA-approved across the relapsing-MS spectrum and developed by Novartis. It is not a controlled substance. In Saudi Arabia, Mayzent is not routinely registered for outpatient dispensing, and access is typically coordinated through the named-patient import pathway.

This guide explains the pathway, documentation your physician prepares, typical timing and cost bands, and where Reserve Meds fits in.

## The clinical situation

Mayzent is an oral sphingosine-1-phosphate (S1P) receptor modulator taken once daily after a titration schedule. Critically, dosing selection and titration depend on CYP2C9 genotype, patients must be genotyped before initiation, and patients with the CYP2C9<sup>3/3</sup> genotype should not take Mayzent. Eligibility anchors to confirmed relapsing MS (including active SPMS) per McDonald criteria, baseline MRI, and the S1P-class cardiovascular, ophthalmologic, and infection monitoring plan. First-dose observation for bradycardia is standard per labeling.

## Is Mayzent legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Saudi Food and Drug Authority (SFDA) named-patient / special-access import framework. The mechanism permits a Saudi Arabia-licensed physician to import a medicine not locally registered when (a) it is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent registered alternative is suitable for the patient's active SPMS phenotype, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented.

## How the pathway works, step by step

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1. **Consultation with your treating neurologist.** MS diagnosis per McDonald criteria, active-SPMS characterisation, MRI documentation, and clinical rationale.
2. **CYP2C9 genotyping.** Required before initiation to select appropriate dose or exclude patients with 3/3 genotype.
3. **Baseline assessment.** CBC, hepatic panel, baseline ECG, ophthalmologic examination for macular oedema risk, varicella zoster antibody status, and first-dose observation plan.
4. **SFDA named-patient application.** The physician or hospital pharmacy files clinical rationale, patient reference, genotype result, titration schedule, and chain-of-custody commitment.
5. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Mayzent from authorised distribution under DSCSA.
6. **Ambient shipment and arrival.** Mayzent ships under controlled ambient conditions; the hospital pharmacy releases the bottle with the titration kit after first-dose observation is scheduled.

## What documentation your physician needs

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- Clinical rationale letter confirming relapsing MS / active SPMS and Mayzent as the indicated therapy
- Verification of Saudi Arabia medical license
- MRI report and McDonald-criteria documentation
- CYP2C9 genotype result
- Baseline CBC, hepatic panel, ECG, ophthalmologic examination, VZV antibody status
- First-dose observation plan
- Planned titration schedule and monitoring plan

Reserve Meds provides a physician documentation kit bundling templates SFDA reviewers expect for S1P-modulator named-patient imports.

## Costs and timing

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Mayzent's US cash-pay drug-only reference cost sits in an indicative 2026 annual range of roughly USD 100,000-110,000 for continuous daily dosing. International logistics, SFDA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a transparent quote at the start of intake. Indicative range.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted, subject to the CYP2C9 genotyping result being in hand.

*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.*

## Reserve Meds's role

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- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and SFDA review.
- **Logistics.** Ambient-controlled shipment to your prescribing hospital.
- **Concierge case lead.** A named point of contact coordinating monthly refills and the ongoing monitoring cadence.

**What we do not do:** We are not the prescriber, do not practise medicine, and are not the dispensing pharmacy. All clinical decisions remain with your treating neurologist.

## Frequently asked

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**Is this legal in Saudi Arabia?** Yes, when executed through the SFDA named-patient framework with appropriate documentation. See our trust and compliance page.

**Is Mayzent a controlled substance?** No. Siponimod is not a scheduled controlled substance.

**Why is CYP2C9 genotyping required?** Mayzent metabolism is CYP2C9-dependent; dose selection is genotype-directed, and 3/3 patients should not take Mayzent per labeling. Your neurologist orders the test before initiation.

**What is first-dose observation?** Because S1P modulators can transiently lower heart rate, the first dose is administered under clinical observation for 6 hours with ECG monitoring, consistent with FDA labeling.

**Will insurance cover this?** Cash-pay is the default. Some Saudi Arabia private insurers consider case by case; we supply documentation but do not process 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.

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### 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.

reservemeds.com · hello@reservemeds.com