Tascenso-Odt

Saudi Arabia · access guide

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

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

A Saudi Arabia family with a child or adolescent (aged 10 years or older) who has been diagnosed with relapsing multiple sclerosis may receive a prescription for Tascenso ODT (fingolimod orally-disintegrating tablet) from their treating paediatric neurologist. Tascenso ODT is FDA-approved specifically for paediatric relapsing MS, and the ODT formulation is designed to make administration more feasible for children and adolescents who find swallowing capsules difficult. In Saudi Arabia, Tascenso ODT is not routinely registered for paediatric outpatient dispensing, and access is typically coordinated through the named-patient import pathway.

This guide explains the pathway, documentation the treating paediatric neurologist prepares, typical timing and cost bands, and where Reserve Meds fits in. A note on scope: Tascenso ODT's paediatric labelling is the reason this guide exists as a distinct document from adult fingolimod access; Reserve Meds coordinates paediatric cases with particular care around dosing, consent, and family support.

The clinical situation

Tascenso ODT is an orally-disintegrating tablet form of fingolimod, the first-generation S1P receptor modulator. It is dosed once daily, 0.25 mg in paediatric patients weighing 40 kg or less, and 0.5 mg in paediatric patients weighing more than 40 kg (dose is weight-banded, not titrated). First-dose cardiac monitoring is required for all patients initiating any fingolimod formulation; the observation window is typically six hours with ECG before and after first dose, given the first-dose bradycardia and conduction-effect profile of the S1P-modulator class.

Eligibility requires a confirmed paediatric relapsing MS diagnosis per McDonald criteria applied to paediatric-onset disease, MRI evidence, and a paediatric-neurology rationale. Before starting, the treating paediatric neurologist will establish a baseline ECG, cardiac review, complete blood count with lymphocyte count, baseline liver function tests, varicella serology, ophthalmologic baseline (macular oedema risk), and skin examination. Live vaccines are avoided during therapy.

Is Tascenso ODT legally importable into Saudi Arabia?

Yes, through the Saudi Food and Drug Authority (SFDA) named-patient import framework, with parallel authority through the Department of Health (DoH) in Abu Dhabi and the Dubai Health Authority (DHA) in Dubai depending on where the prescribing paediatric-neurology facility sits. Paediatric named-patient imports receive particular regulatory attention around dose verification and consent documentation; the mechanism permits import when the medicine is FDA-approved for the paediatric indication, no clinically equivalent registered alternative is suitable, the treating physician accepts clinical responsibility, and chain of custody is documented.

How the pathway works, step by step

1. **Consultation with the treating paediatric neurologist.** Confirmation of paediatric relapsing MS, MRI review, and clinical rationale for an S1P modulator in the paediatric setting.
2. **Baseline workup.** ECG, cardiac review, CBC with lymphocyte count, LFTs, varicella serology, ophthalmology baseline, weight documentation for dose banding.
3. **SFDA named-patient application.** The physician or hospital pharmacy files the application including paediatric clinical rationale, patient reference, dose band, monitoring plan, and parental consent documentation.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Tascenso ODT from authorised distribution under DSCSA.
5. **Ambient shipment.** Tascenso ODT ships under controlled ambient conditions with chain-of-custody documentation.
6. **First-dose observation.** The dispensing facility arranges the six-hour first-dose cardiac monitoring window per FDA labelling. Subsequent daily doses are given at home by the family.

What documentation your physician needs

- Clinical rationale letter confirming paediatric relapsing MS and Tascenso ODT as the indicated therapy
- Verification of Saudi Arabia medical licence with paediatric-neurology scope
- MRI report supporting the diagnosis
- Baseline ECG and cardiac review
- CBC with lymphocyte count and LFTs
- Varicella serology
- Ophthalmology baseline
- Weight documentation for dose banding (0.25 mg vs 0.5 mg)
- Parental consent documentation

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

Typical costs and indicative timing

Tascenso ODT's US cash-pay reference cost sits in an indicative 2026 annual range of roughly USD 95,000-110,000. International logistics, SFDA documentation handling, and concierge coordination add incremental cost. Reserve Meds issues a transparent quote at the start of intake. These figures are indicative drug-only reference pricing.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete SFDA application is submitted. First-dose cardiac observation is scheduled with the hospital and may add a half-day to the practical start date. Monthly refills 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. Paediatric cases are triaged with particular care.

Reserve Meds's role

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for the paediatric neurologist and SFDA review.
- **Logistics.** Ambient-controlled shipment to the prescribing paediatric-neurology facility.
- **Concierge case lead.** A named point of contact supporting the family and the treating team through monthly cycles.

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 the treating paediatric neurologist.

Frequently asked

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

Why the ODT formulation? The orally-disintegrating tablet is designed to be easier for children and adolescents to take than a capsule, the drug substance (fingolimod) is the same, the delivery format is child-friendly.

Why six-hour first-dose monitoring? First-dose bradycardia is a labelled effect of all fingolimod formulations. The observed monitoring window applies regardless of age.

Is paediatric consent different? Yes. Parental consent plus age-appropriate assent is required, and the SFDA application reflects this.

Will private insurance cover this? Cash-pay is the default. Some Saudi Arabia private insurers consider paediatric named-patient imports 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.

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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