

Ongentys

Saudi Arabia · access guide

How to access Ongentys 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 Parkinson's disease experiencing end-of-dose OFF-episodes on levodopa/carbidopa may receive a prescription for Ongentys (opicapone) from their treating neurologist or movement-disorder specialist. Ongentys is FDA-approved as adjunctive therapy for OFF-episodes and developed by Neurocrine Biosciences (licensed from BIAL). It is not a controlled substance. In Saudi Arabia, Ongentys 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

Ongentys is a once-daily catechol-O-methyltransferase (COMT) inhibitor taken at bedtime (at least one hour before or after levodopa-containing medicines) at 50 mg. COMT inhibition prolongs levodopa's effect, reducing OFF-time. Eligibility anchors to established Parkinson's disease, optimised levodopa/carbidopa regimen, and persistent end-of-dose OFF-episodes. Your neurologist will characterise OFF-time (patient diary, motor fluctuations), confirm optimal levodopa dose, and screen for dyskinesia tolerance before adding a COMT inhibitor.

Is Ongentys legally importable into Saudi Arabia?

Yes, through the 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, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented. Parkinson's OFF-episode management has a small set of COMT inhibitor options, and the choice of agent is guided by the clinical picture.

How the pathway works, step by step

1. **Consultation with your treating neurologist.** Parkinson's diagnosis, levodopa regimen optimisation, OFF-episode diary documentation.
2. **Baseline assessment.** Motor fluctuation profile, dyskinesia tolerance, hepatic function (COMT class has historical hepatic concerns, opicapone's profile is distinct, but baseline hepatic panel is documented).
3. **SFDA named-patient application.** The physician or hospital pharmacy files clinical rationale, patient reference, and dosing plan.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Ongentys from authorised distribution under DSCSA.
5. **Ambient shipment.** Ongentys ships under controlled ambient conditions with chain-of-custody documentation.
6. **Arrival and dispensing.** The hospital pharmacy releases the bottle with dosing instructions (bedtime dosing, timing relative to levodopa).

What documentation your physician needs

- Clinical rationale letter confirming Parkinson's with OFF-episodes and Ongentys as the indicated adjunct
- Verification of Saudi Arabia medical license
- Levodopa/carbidopa regimen documentation
- OFF-episode diary evidence
- Baseline hepatic panel
- Planned dosing schedule (bedtime)

Reserve Meds provides a physician documentation kit bundling templates SFDA reviewers expect for Parkinson's adjunct named-patient imports.

Costs and timing

Ongentys's US cash-pay drug-only reference cost sits in an indicative 2026 annual range of roughly USD 14,000-17,000 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.

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

- **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.

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

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 Ongentys a controlled substance? No. Opicapone is not a scheduled controlled substance.

How does Ongentys compare with entacapone or tolcapone? Ongentys is a once-daily COMT inhibitor with a distinct pharmacokinetic profile; entacapone is dosed with each levodopa dose; tolcapone has known hepatic concerns. Your neurologist selects based on adherence, tolerability, and hepatic risk.

What is the dosing timing? Once daily at bedtime, at least one hour before or after levodopa-containing medicines. Your neurologist will clarify the interaction with your specific regimen.

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.

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.

reservemed.com · hello@reservemed.com