

Austedo

India · access guide

How to access Austedo (deutetrabenazine) from India: the CDSCO named-patient pathway

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-05-16

Quick orientation

Austedo (deutetrabenazine) is an FDA-approved VMAT2 inhibitor (deuterated) developed by Teva Pharmaceuticals, first approved in 2017. It is a vesicular monoamine transporter 2 (VMAT2) inhibitor with selective deuterium substitution that prolongs half-life and permits twice-daily dosing with smoother plasma exposure than first-generation tetrabenazine. FDA-approved indications cover chorea associated with Huntington's disease and tardive dyskinesia in adults. Austedo is taken orally twice daily with food, starting at 6 mg twice daily and titrated weekly by 6 mg increments to the lowest effective dose, with a maximum of 24 mg twice daily. An extended-release once-daily formulation (Austedo XR) is also FDA-approved.

US WAC reference: approximately USD 80,000 per year at typical maintenance dosing (commonly 24 to 48 mg daily, divided). approximately USD 6,500 to 7,000 per month at US WAC.

Why Indian patients route Austedo via the named-patient pathway

India's pharmaceutical access framework is governed by the Central Drugs Standard Control Organisation (CDSCO) under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Rule 36 of these Rules provides a named-patient import mechanism that allows a licensed physician (or the patient, with prescription) to import a specific medicine for a specific patient where the locally available channel does not meet the clinical need.

The most common Rule 36 triggers for Austedo are: (a) the prescribed presentation, strength, or formulation is not locally registered or not currently in stock at the patient's tertiary centre, (b) registration of a newer indication has lagged behind the FDA approval, (c) the patient requires the originator manufacturer for continuity from a prior course of treatment, or (d) local supply has been inconsistent and the treating physician judges that bridge supply is clinically necessary.

Deutetrabenazine is not broadly stocked outside select Indian tertiary movement-disorder centres, and tardive dyskinesia in particular is frequently undertreated when first-generation tetrabenazine tolerability becomes limiting. Because Austedo is shelf-stable (stored at room temperature 20 to 25 degrees Celsius), logistics are simpler than for cold-chain biologics, but presentation fidelity (correct strength, correct manufacturer batch, correct expiry) still requires deliberate coordination.

The Indian tertiary-hospital ecosystem - Apollo, Tata Memorial, AIIMS, CMC Vellore, Max, Kokilaben, Medanta, Fortis, Manipal - has the movement-disorder neurologists and psychiatrists, infusion-suite or self-injection-training infrastructure, and laboratory monitoring capacity to support Austedo therapy once supply is in hand. The named-patient channel exists to bridge the supply side; the clinical infrastructure is already there.

Indian payers (public and private) treat Austedo unevenly. Public-channel access is limited. Private insurers and corporate plans sometimes reimburse named-patient imports on case-by-case approval but typically require prior-authorisation and documented failure or inadequate response on conventional therapy. Most patients budget for cash-pay as the default and submit for reimbursement after the fact.

The CDSCO named-patient pathway for Austedo, step by step

1. **Consultation with your treating neurologist (movement disorders) or psychiatrist.** Eligibility for Austedo is a clinical decision based on diagnosis, prior therapy, and indication-specific criteria.
2. **Clinical rationale documented.** Your physician documents the indication, dose, prior-therapy history, and the reason the local channel does not meet the need (the formulary-gap or supply-gap justification under Rule 36).
3. **CDSCO application filed.** Your physician (or the importing pharmacy partner) files the personal-import / named-patient documentation with CDSCO. The application identifies the patient (anonymised reference), specifies the medicine, dose, and quantity, and attaches the prescription and clinical letter.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner under DSCSA chain-of-custody, with manufacturer-direct sourcing where possible.
5. **Shipment.** Standard ambient shipment with documented chain of custody from US dispensing pharmacy to Indian tertiary centre.
6. **Arrival and administration.** Austedo is delivered to the designated tertiary centre or, where the presentation supports it, directly to the patient for at-home administration. Austedo is taken orally twice daily with food, starting at 6 mg twice daily and titrated weekly by 6 mg increments to the lowest effective dose, with a maximum of 24 mg twice daily.
7. **Ongoing coordination.** Reserve Meds supports re-supply cadence aligned to the dosing schedule and coordinates documentation for follow-up CDSCO filings if required.

Where Austedo is administered or dispensed in India

Indian tertiary centres with the movement-disorder neurologists and psychiatrists infrastructure to support Austedo typically include:

- **Apollo Hospitals, Indraprastha (Delhi)** and the broader Apollo network across Chennai, Hyderabad, Bengaluru, and Mumbai
- **Tata Memorial Hospital (Mumbai)** for oncology-adjacent and complex-comorbidity cases
- **All India Institute of Medical Sciences, AIIMS (Delhi)** for tertiary specialty consultations
- **Christian Medical College, CMC Vellore** for neurologist and related care
- **Max Super Speciality Hospital, Saket (Delhi)**
- **Kokilaben Dhirubhai Ambani Hospital (Mumbai)**
- **Medanta - The Medicity (Gurgaon)**
- **Fortis Memorial Research Institute (Gurgaon)**
- **Manipal Hospitals (Bengaluru)** and the broader Manipal network

Choice of centre is a clinical decision; Reserve Meds coordinates supply to the centre your treating physician designates and does not direct referral.

Real cost picture for Austedo in India via the named-patient pathway

The cash-pay total for Austedo via this channel decomposes into three components: drug cost, logistics, and concierge coordination.

- **Drug cost (US WAC reference).** approximately USD 80,000 per year at typical maintenance dosing (commonly 24 to 48 mg daily, divided). At an indicative 83 INR per USD reference, annual drug-only cost translates to roughly INR 66 lakh before logistics and concierge fees.
- **Logistics and 3PL.** Ambient shipment with customs handling. Indicative incremental cost is in the high-hundreds USD per shipment depending on quantity.
- **Reserve Meds concierge fee.** Tiered as a percentage of drug cost, disclosed at intake on the firm quote.

Reserve Meds issues an indicative range at the start of intake and a firm delivered quote after your physician's documents are uploaded. We do not collect a deposit at intake; payment is wired only after a firm quote is accepted. See our cost-range methodology.

Some Indian private insurers reimburse named-patient imports on case-by-case approval. We supply documentation for your submission; reimbursement is not guaranteed and is not promised by Reserve Meds.

Typical timeline

From the moment a complete CDSCO application is filed to the moment Austedo arrives at the designated Indian tertiary centre, the indicative timeline is 10 to 21 days. CDSCO review of a well-documented Rule 36 application typically takes 5 to 10 working days; US-side sourcing and release add 2 to 5 working days. For ambient shipments, transit is typically 3 to 7 days from US release to Indian tertiary-centre receipt.

Re-supply is generally faster (7 to 14 days end-to-end) once the pathway is established and the patient profile is on file.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, flag that when you

What your physician needs to provide

The CDSCO named-patient application is built around the physician's clinical letter and the prescription. Your treating neurologist (movement disorders) or psychiatrist will typically need to provide:

- **Clinical justification letter.** Diagnosis, prior-therapy history, response and tolerability of prior agents, and the clinical rationale for Austedo as the indicated next step.
- **MCI / NMC registration.** Verification of the physician's Indian medical-council registration (Medical Council of India, now National Medical Commission).
- **Patient identifier.** Anonymised reference where possible, full identification where the application requires it.
- **Prescription.** Brand name, strength, dose, quantity, and duration of supply.
- **Formulary-gap or supply-gap justification.** Specific statement of why the local channel does not meet the clinical need for this patient (the Rule 36 trigger).
- **Monitoring plan.** Baseline and periodic assessment for depression and suicidality (boxed-warning items in huntington's disease), qt-interval review in patients on qt-prolonging agents, and cyp2d6 metaboliser status when daily dose exceeds 24 mg.
- **Adverse-event reporting commitment.** A statement that the physician will report any serious adverse events through CDSCO pharmacovigilance channels.

Reserve Meds provides a physician documentation kit that bundles the templates CDSCO reviewers expect and a worked example for your physician's reference.

Frequently asked

How long until chorea or dyskinesia improvement is seen? Most patients see measurable improvement within four to eight weeks of reaching maintenance dose, with full response assessed at twelve weeks.

Can Austedo be switched from tetrabenazine? Yes. Your neurologist follows the label conversion ratio. We coordinate the resupply cadence to bridge the switch.

Does Austedo require any genetic testing? CYP2D6 metaboliser-status testing is recommended before exceeding 24 mg total daily dose. Many Indian tertiary labs offer this assay.

Is Austedo XR (once daily) available through this pathway? Yes. The XR formulation is FDA-approved and is a coordinatable presentation if your neurologist prescribes it specifically.

What is the suicidality warning about? Austedo carries a boxed warning for depression and suicidality in Huntington's disease. Your neurologist will document a baseline mental-health assessment and follow standard monitoring intervals.

Is this legal? Yes, when executed through the CDSCO Rule 36 personal-import / named-patient framework. See our trust and compliance page.

Can Reserve Meds promise insurance reimbursement? No. Reimbursement is determined by your insurer and your specific policy. We supply documentation; we do not promise outcomes.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Austedo specifically, we provide:

- **Sourcing.** US-licensed specialty wholesale partner under DSCSA chain-of-custody, manufacturer-direct where possible.
- **Documentation.** CDSCO-ready documentation package for your physician and a worked example for the Rule 36 application.
- **Logistics.** Ambient shipment, customs handling, and delivery to the designated tertiary centre.
- **Concierge case lead.** A named point of contact throughout intake, application, shipment, and re-supply cadence.

What we do not do. We are not the prescriber. We do not practice medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating physician. Our case team responds to intakes within 24 to 48 hours. **If Austedo is already available to you locally for your indication, stay on the local channel.**

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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