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Ingrezza access in the UAE: the EDE named-patient pathway

How patients in the United Arab Emirates with tardive dyskinesia or Huntington's disease chorea access Ingrezza (valbenazine), an FDA-approved VMAT2 inhibitor not registered locally.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

This page describes the named-patient pathway for adults with diagnosed tardive dyskinesia or Huntington's disease chorea whose treating specialist has selected valbenazine and for whom no locally registered equivalent is suitable.

Section 1. Quick orientation

Ingrezza is the brand name for valbenazine, an oral once-daily selective vesicular monoamine transporter 2 (VMAT2) inhibitor manufactured by Neurocrine Biosciences. Valbenazine carries two FDA-approved indications in adults: tardive dyskinesia, approved in April 2017 as the first medication ever FDA-approved for this condition, and chorea associated with Huntington's disease, approved in August 2023 on the basis of the phase 3 KINECT-HD trial. Valbenazine is not registered with the Emirates Drug Establishment or with MOHAP for commercial sale in the UAE. For adults in the UAE with persistent movement symptoms whose treating psychiatrist or neurologist has selected valbenazine, the lawful access route is the unregistered-medicine personal-use import permit administered by the EDE. Reserve Meds coordinates the US-side sourcing, documentation kit, and international logistics under a single named coordinator. The clinical decision remains with your treating specialist. **Reserved for you.**

Section 2. Why UAE patients need Ingrezza through a named-patient pathway

The UAE operates one of the most developed pharmaceutical regulatory environments in the Gulf Cooperation Council. The Emirates Drug Establishment, which assumed 44 core regulatory services from MOHAP on 29 December 2025 under Federal Decree-Law No. 38 of 2024, maintains the national drug register and the unregistered-medicine personal-use import permit pathway. Three structural access gaps recur in UAE patient cases. For Ingrezza, the dominant gap is the third pattern, not registered in the UAE at all.

Neurocrine Biosciences has not pursued EDE marketing authorisation for valbenazine, and the drug is not stocked through UAE retail or hospital pharmacy networks. For UAE psychiatrists who recognise tardive dyskinesia in patients on long-term antipsychotic therapy, the typical local response has historically been dose reduction of the causative antipsychotic or watchful waiting. An FDA-approved selective VMAT2 inhibitor changes the conversation, but it cannot be dispensed locally without an import permit. For neurologists managing Huntington's disease families in the UAE, valbenazine's once-daily dosing and selectivity for VMAT2 make it the preferred chorea-control option for those who can access it, but local pharmacy stocking is

essentially nonexistent. The named-patient pathway is the only lawful route to authentic US-supplied Ingrezza in the UAE.

Section 3. The EDE named-patient pathway for Ingrezza

The federal pathway for a UAE-licensed physician to obtain a medicine that is not registered locally is the unregistered-medicine import permit, administered through the EDE portal at ede.gov.ae from 29 December 2025. The framework allows hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority, in this case the US FDA, and a clinically equivalent locally registered alternative is not suitable. UAE compassionate-use provisions describe the use of a medical product outside of clinical trials when no alternative treatment options are available, which fits both the tardive dyskinesia and the Huntington chorea use cases.

A complete application typically includes a clinical justification letter from the treating physician, the physician's UAE medical license verification (MOHAP for Northern Emirates, DHA for Dubai, DOH for Abu Dhabi, or Sharjah Health Authority), an anonymised patient identifier where the EDE submission allows, full product details (Ingrezza, valbenazine, Neurocrine Biosciences, 40 mg, 60 mg, or 80 mg capsules, 30-count bottle), the requested quantity and intended treatment duration, the dispensing facility's pharmaceutical establishment license, and a chain-of-custody plan from the US specialty pharmacy through the importer to the dispensing pharmacy.

The cell-specific clinical-justification angle for Ingrezza splits by indication. For tardive dyskinesia, the letter documents the diagnosis and severity (typically AIMS, Abnormal Involuntary Movement Scale, score), the causative dopamine receptor blocking agent and exposure history, the failure or inadequacy of antipsychotic dose reduction or substitution, and the absence of a locally registered VMAT2 inhibitor option. For Huntington's disease chorea, the letter documents genetic confirmation of HD (CAG repeat expansion in HTT), the Unified Huntington's Disease Rating Scale (UHDRS) Total Motor Score where available, baseline mood and suicidality screening, and the rationale for valbenazine over tetrabenazine or deutetrabenazine. Approval timelines for routine cases are typically 5 to 15 business days; HD chorea cases with the boxed warning for depression and suicidality may extend to 3 to 4 weeks at the authority's discretion.

Section 4. Where Ingrezza gets dispensed in the UAE

The relevant capability for Ingrezza is psychiatry (for tardive dyskinesia) or neurology (for HD chorea), supported by a hospital outpatient pharmacy able to dispense an oral medicine. The room-temperature handling profile of valbenazine means no specialised cold-chain pharmacy infrastructure is required. Cleveland Clinic Abu Dhabi (M42 group, Al Maryah Island) and Sheikh Khalifa Medical City (SEHA network, Abu Dhabi) carry strong neurology and psychiatry service lines and routinely file unregistered-medicine permits. American Hospital Dubai (Mayo Clinic Care Network member), King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City similarly hold pharmaceutical establishment licenses. NMC Healthcare's flagship Dubai and Abu Dhabi sites also handle these cases.

For patients whose treating specialist practices at a smaller hospital or a clinic without internal import infrastructure, the common pattern is to route through a Dubai- or Abu Dhabi-based specialty importer that holds a pharmaceutical establishment license and files the EDE application on the prescribing physician's behalf. The importer performs customs clearance and delivers the medicine to the prescribing hospital's outpatient pharmacy under chain-of-custody

documentation. Patients resident in the Northern Emirates typically route to a Dubai or Abu Dhabi centre where their treating physician holds joint privileges or where the case is co-managed with a UAE-licensed specialist. For Huntington's disease cases specifically, families are typically already connected to a tertiary neurology service, which simplifies hospital selection.

Section 5. Real cost picture for Ingrezza in the UAE

The UAE dirham is pegged to the US dollar at approximately 3.67 AED to 1 USD. Reserve Meds quotes are itemised, not bundled.

- **Drug cost reference.** US wholesale acquisition cost for Ingrezza at launch in 2017 was approximately USD 5,275 per 30-count bottle of 40 mg capsules. Subsequent annual list-price adjustments have moved the figure upward; 2026 public references cite a 28-capsule bottle of 40 mg at approximately USD 7,900 and 80 mg at approximately USD 8,700, working out to an annual list price of approximately USD 103,000 to USD 113,000 at maintenance dosing. International cash-pay procurement prices above US WAC in line with NPP norms.
- **International logistics.** Ambient room-temperature shipping for an oral capsule, USD 400 to 1,500 (approximately AED 1,500 to 5,500) depending on destination emirate and urgency. No cold chain is required.
- **Regulatory and concierge.** EDE permit fees and customs handling are nominal relative to the drug cost. Reserve Meds' concierge coordination fee is itemised separately on every firm quote.

Daman National Health Insurance (operator of the Thiqa programme for UAE nationals), GIG Gulf, Sukoon Insurance, ADNIC, and Orient Insurance each handle named-patient imports case by case. Coverage for movement-disorder therapy varies. Some plans cover psychiatric and neurological specialty drugs on prior authorisation; cash-pay is the default posture. Neurocrine's US-only INBRACE access program, copay support, and patient assistance do not extend to international patients; Reserve Meds does not represent them as available outside the United States.

Section 6. Typical timeline for Ingrezza in the UAE

The room-temperature, no-reconstitution handling profile keeps the supply chain straightforward. End-to-end timing is governed by the regulatory layer. EDE permit issuance for a routine tardive dyskinesia case is typically 5 to 15 business days. Huntington's disease chorea cases, with the boxed warning for depression and suicidality and the need for documented baseline mood screening, can extend the review to 3 to 4 weeks at the authority's discretion. US-side procurement runs in parallel through Neurocrine's specialty pharmacy channel; chain-of-custody verification of manufacturer serial number and lot is part of the receiving documentation given the high per-bottle value. Once the permit is issued, ambient air freight clears UAE customs within 2 to 5 business days. Hospital pharmacy receipt and release to the treating physician completes the cycle. A reasonable end-to-end estimate from intake to first dose in hand is 3 to 6 weeks for a first import; established refill cycles compress to 2 to 3 weeks. These ranges are typical, not promises.

Section 7. What your physician needs to provide

The clinical justification letter is the cornerstone of the EDE application. For Ingrezza, the letter content varies by indication. For tardive dyskinesia, the letter documents the diagnosis, the causative agent and exposure history (typical or atypical antipsychotic, antiemetic with dopamine-blocking activity), the AIMS score where available, prior management attempts (dose reduction, substitution to a lower-D2-affinity agent) and their outcomes, and the absence of a locally registered VMAT2 inhibitor option in the UAE. For Huntington's disease chorea, the letter documents the HD diagnosis with CAG repeat confirmation, the UHDRS Total Motor Score, baseline mood and suicidality screening (Columbia Suicide Severity Rating Scale or equivalent), and a treatment plan that includes ongoing depression and suicidality monitoring throughout therapy.

Dosing in the letter aligns with the FDA-approved label. For tardive dyskinesia: 40 mg orally once daily for the first week, then 80 mg once daily as the recommended dose; a maintenance dose of 40 mg or 60 mg may be considered for patients who do not tolerate 80 mg. For Huntington's chorea: start at 40 mg once daily, titrate weekly in 20 mg increments based on chorea reduction, tolerability, and clinical assessment, up to a maximum of 80 mg once daily. Dose reductions to a maximum of 40 mg once daily are required for patients on strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or known CYP2D6 poor metabolizers. Warnings to monitor include depression and suicidality (boxed warning, HD chorea indication), somnolence, QT prolongation in susceptible patients, parkinsonism, and neuroleptic malignant syndrome. The treating physician's UAE medical license number, issuing authority, and the dispensing facility's pharmaceutical establishment license complete the package.

Section 8. Common questions about Ingrezza in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover this? Each insurer assesses named-patient imports case by case. We do not promise coverage. Coverage for chronic psychiatric and neurological specialty therapy varies. Reserve Meds supplies the documentation that allows your insurer to assess; the claim sits with you or your hospital. Cash-pay is the default posture.

Will my DHA-licensed psychiatrist's letter be sufficient for a tardive dyskinesia case?

Yes. Any UAE-licensed psychiatrist or neurologist practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. For Huntington's chorea cases, a neurologist's letter is the natural fit; for tardive dyskinesia, either a psychiatrist or a neurologist can sign.

What is the safety profile? The FDA label for valbenazine in the Huntington's disease chorea indication carries a boxed warning for depression and suicidality, reflecting the underlying psychiatric vulnerability of the HD population. This boxed warning is specific to the HD chorea indication and is not present in the tardive dyskinesia label. The most commonly reported adverse reaction across both indications is somnolence. Other notable warnings include QT prolongation, parkinsonism, and neuroleptic malignant syndrome.

What is the monitoring requirement? For HD patients, baseline and ongoing assessment of mood, suicidal ideation, and depressive symptoms is required, with caregivers and clinicians both involved. Sedation should be monitored, particularly during initiation and titration. QT assessment is appropriate in patients with congenital long QT, on QT-prolonging medications, or known CYP2D6 poor metabolizers.

How is Ingrezza different from deutetrabenazine (Austedo)? Both are selective VMAT2 inhibitors FDA-approved for tardive dyskinesia and Huntington's disease chorea. Once-daily dosing is the most cited practical advantage of valbenazine; deutetrabenazine is dosed twice daily with food. Tolerability and side-effect profile differ. Reserve Meds does not advise on which VMAT2 inhibitor to use; that conversation belongs with the treating specialist.

Can the capsules be opened for patients with swallowing difficulty? Capsules should be taken whole unless the Sprinkle formulation is prescribed. The Sprinkle formulation is supplied in unit-dose packets for patients who cannot swallow capsules and broadens administration options without altering dosing.

Section 9. Where Reserve Meds fits in Ingrezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace your physician, do not replace the Emirates Drug Establishment, and do not replace your dispensing pharmacy. For Ingrezza specifically, the orchestration we provide is a documentation kit your treating specialist uses to assemble the EDE application with indication-appropriate framing, US-side procurement through Neurocrine's specialty pharmacy channel with manufacturer-serial-number chain-of-custody verification, ambient air-freight logistics under pharmaceutical-grade packaging, customs documentation aligned to the permit, and a single named coordinator who stays with your case from intake through delivery. For Huntington's disease chorea cases, the boxed warning for depression and suicidality is flagged in the patient-facing materials and confirmed acknowledged by the treating neurologist in the case file. No prior Reserve Meds case experience exists for Ingrezza at the date of this page. Standard NPP coordination applies.

Section 10. Next step

If your treating psychiatrist or neurologist has selected Ingrezza for tardive dyskinesia or Huntington's chorea and you are based in the UAE, the next step is the waitlist. We confirm eligibility within 24 to 48 hours and send a documentation kit to your physician. **Reserved for you.**

This guide is informational, not medical or legal advice. The named-patient framework requires a licensed UAE physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology >

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