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## Ingrezza access in Pakistan: the DRAP Special Permission pathway

How adults in Pakistan with tardive dyskinesia or chorea associated with Huntington's disease access Ingrezza, the first selective VMAT2 inhibitor approved in the United States, when valbenazine is not registered locally.

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

*This page describes the DRAP Special Permission Personal Use Import pathway for Ingrezza for adults in Pakistan living with tardive dyskinesia or with chorea associated with Huntington's disease. We use respectful psychiatric vocabulary throughout, in keeping with how families and clinicians actually speak about these conditions.*

### Section 1. Quick orientation

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Ingrezza (valbenazine) is an oral small-molecule selective vesicular monoamine transporter 2 (VMAT2) inhibitor manufactured by Neurocrine Biosciences, Inc. of San Diego, California. The US Food and Drug Administration approved Ingrezza for the treatment of tardive dyskinesia (TD) in adults on 11 April 2017, making valbenazine the first medication ever approved in the United States for this condition. The FDA approved a second indication for chorea associated with Huntington's disease (HD) in adults on 18 August 2023, based on the phase 3 KINECT-HD trial. A Sprinkle formulation for patients who cannot swallow capsules broadens administration options for both indications. Valbenazine is not registered with the Drug Regulatory Authority of Pakistan (DRAP). For adults in Pakistan whose treating psychiatrist (for tardive dyskinesia) or neurologist (for Huntington's chorea) has identified valbenazine as the appropriate option, the lawful pathway is the DRAP Special Permission for Personal Use Import (also referred to as the No Objection Certificate for Personal Use Import) filed through the DRAP Online Import and Export System (OIES). Reserve Meds coordinates the US-side sourcing through Neurocrine's specialty-pharmacy channel, the regulatory documentation, the international logistics, and a single named coordinator who stays with the family throughout the case. **Reserved for you.**

### Section 2. Why patients in Pakistan need Ingrezza through a named-patient pathway

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Pakistan's specialty drug market gap is most pronounced in conditions where the local patient population for any one drug is small relative to the cost of a full DRAP registration filing, and where the local clinical community has historically had limited treatment options to offer. Tardive dyskinesia, which arises from long-term exposure to dopamine receptor blocking agents including antipsychotics and certain antiemetics, is meaningfully prevalent in Pakistan because antipsychotic prescribing for schizophrenia, bipolar disorder, and other psychiatric conditions has been routine for decades. Psychiatrists in Karachi, Lahore, Islamabad, and across the public-sector psychiatric service network frequently recognise TD in patients on chronic antipsychotic

therapy yet historically have had no approved VMAT2 inhibitor to offer beyond dose reduction of the causative antipsychotic. Huntington's disease is rare globally and rare in Pakistan, but families with HD do exist and the chorea component is one of the most clinically distressing features of the disease.

The structural reason valbenazine reaches Pakistani patients through the Personal Use Import pathway is durable. Neurocrine has not filed for DRAP registration, and the commercial volume in Pakistan does not justify the registration economics at present. Tetrabenazine, the older nonselective VMAT inhibitor, is available in some Pakistani markets and is approved for Huntington's chorea but not for tardive dyskinesia, and it carries a heavier side-effect burden than the selective VMAT2 inhibitors. Deutetrabenazine (Austedo), the other FDA-approved selective VMAT2 inhibitor approved for both TD and HD chorea, is also not registered with DRAP and reaches Pakistani patients through the same Personal Use Import pathway. For psychiatrists with TD patients and neurologists with HD families seeking chorea control, the named-patient route is the lawful path to a selective VMAT2 inhibitor.

### **Section 3. The DRAP Special Permission pathway for Ingrezza**

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DRAP regulates the import of medicines through the Quality Assurance and Laboratory Testing Division's Import and Export Section. For unregistered medicines required by a specific patient, DRAP issues a Special Permission, also referred to as the No Objection Certificate (NOC) for Personal Use Import. Applications are filed through DRAP's Online Import and Export System (OIES), with patient-level applications submitted by the patient or applicant directly on the portal and institutional applications filed by the hospital pharmacy.

The application package for a Personal Use Import of Ingrezza typically includes a clinical justification letter from the treating psychiatrist (for TD) or neurologist (for HD chorea), the prescribing physician's PMDC license verification, the patient identifier (CNIC for adults), the product details (Ingrezza 40 mg, 60 mg, or 80 mg capsules in 30-count bottles, or the Ingrezza Sprinkle unit-dose packets where swallowing capsules is a concern, Neurocrine NDC, requested pack size), the dispensing facility license, a Neurocrine or authorised distributor letter confirming the product is genuine and was sourced through the legitimate US specialty-pharmacy supply chain, and the chain-of-custody plan.

The cell-specific clinical-justification angle for Ingrezza is the diagnosis confirmation and the local-unavailability statement. For tardive dyskinesia, the psychiatrist's letter ideally documents the causative antipsychotic exposure history (drug, duration, indication), the TD diagnosis with reference to a clinician-administered movement-disorder assessment (Abnormal Involuntary Movement Scale or AIMS is the most common reference), the prior management attempts (dose reduction of the causative agent, switch to a lower-TD-risk antipsychotic where clinically possible), and the rationale for selecting valbenazine over deutetrabenazine (once-daily dosing is the most cited practical advantage; deutetrabenazine is dosed twice daily with food). For Huntington's chorea, the neurologist's letter ideally references the genetic confirmation of HD where available, the chorea severity assessment (Unified Huntington's Disease Rating Scale where used), and the patient's psychiatric status given the boxed warning. The local-unavailability statement is important: the letter notes that no approved VMAT2 inhibitor is registered in Pakistan and that tetrabenazine, where available, is either contraindicated for the indication (TD) or carries a less favourable side-effect profile (HD). The planned dose schedule (starting 40 mg once daily; titrating per the indication-specific schedule up to 80 mg once daily as recommended) and the monitoring plan are also on the application. Routine personal-use

cases typically clear in four to eight weeks from a complete submission; complex cases involving novel mechanisms can extend to ten to sixteen weeks.

## Section 4. Where Ingrezza gets dispensed in Pakistan

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Ingrezza is a small-molecule oral capsule, shelf-stable at controlled room temperature (typically labelled 20 to 25 degrees Celsius with excursions permitted between 15 and 30 degrees Celsius). It does not require refrigeration or reconstitution. The product ships in standard pharmacy bottles, typically a 30-count bottle of a single strength (40 mg, 60 mg, or 80 mg capsules). The Ingrezza Sprinkle formulation is supplied in unit-dose packets for patients with swallowing difficulty. The dispensing-facility footprint in Pakistan is therefore broad: any licensed hospital outpatient pharmacy or DRAP-licensed import pharmacy with institutional credentials to receive an unregistered medicine can serve as the dispensing point.

For tardive dyskinesia cases, Aga Khan University Hospital (AKUH) Department of Psychiatry in Karachi, the Institute of Psychiatry at Rawalpindi Medical University, the Department of Psychiatry at Liaquat National Hospital, the psychiatry services at Combined Military Hospitals (CMH) Rawalpindi and CMH Lahore, the Punjab Institute of Mental Health in Lahore, and the Department of Psychiatry at Shifa International Hospital in Islamabad collectively provide the institutional infrastructure for case management. For Huntington's chorea cases, the AKUH Department of Neurology, Shifa International Department of Neurology, Liaquat National Department of Neurology, and the neurology services at the Combined Military Hospitals network handle the smaller HD caseload that exists in Pakistan. The Children's Hospital and Institute of Child Health in Lahore handles paediatric movement disorders where the dispensing physician is on staff, though Ingrezza is approved for adult use only and paediatric cases are not within scope. For psychiatrists and neurologists in private practice or at smaller institutions, the typical route is to partner with a DRAP-licensed specialty importer based in Karachi or Lahore.

## Section 5. Real cost picture for Ingrezza in Pakistan

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Reserve Meds quotes in US dollars and accepts USD wire transfers from any USD-accessible source. The Pakistani Rupee has been volatile across the last several years; as of May 2026 the USD to PKR rate is in the 278 to 280 range. Quoting in USD insulates the patient from intra-case currency drift.

- **Drug cost reference.** Public pricing sources in 2026 cite Ingrezza at approximately USD 7,900 per 28-capsule bottle of 40 mg and approximately USD 8,700 per bottle of 80 mg, working out to an approximate annual list price range of USD 103,000 to USD 113,000 at maintenance dosing. These are list prices and do not reflect rebates, US commercial copay assistance, or international named-patient transaction pricing, which is set independently of US WAC and varies by jurisdiction. Neurocrine's US INBRACE programme (copay support, patient assistance, bridge supply) is US-only and not transferable to international patients. At the prevailing PKR rate the maintenance annualised list reference corresponds to approximately PKR 28 to 31 million.
- **International logistics.** Standard ambient pharmaceutical air freight via DHL Medical Express or FedEx Priority Overnight International with pharma-grade packaging. No cold-chain surcharge applies. The typical logistics envelope for a small-molecule consignment to Karachi or Lahore is USD 400 to USD 1,500 depending on pack volume and the carrier route.

- **Regulatory documentation handling.** DRAP OIES filing support, chain-of-custody documentation tying the consignment back through Neurocrine's specialty-pharmacy supply chain (this drug is not on open wholesale distribution in the US, so the authenticity-attestation work is more involved than for an open-distribution small molecule), FBR Customs coordination, and the dispensing-facility handoff documentation.
- **Reserve Meds concierge fee.** Itemised separately on every firm quote, covering the single named coordinator and the case management through delivery and refill.

Pakistan's private health insurers (State Life, Adamjee, EFU, Jubilee, IGI, Pak-Qatar Family Takaful) typically do not reimburse named-patient imports of unregistered specialty psychiatric or neurological drugs at this price point. The Sehat Sahulat Program's Rs. 1,000,000 per family per year ceiling does not stretch to cover an Ingrezza maintenance regimen at WAC. Cash-pay funded through patient and family resources, often supplemented by overseas remittances from relatives in Saudi Arabia, the UAE, the UK, the US, and Canada, is the practical funding posture for chronic VMAT2-inhibitor therapy.

## Section 6. Typical timeline for Ingrezza in Pakistan

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From the point at which Reserve Meds receives a complete documentation package (psychiatrist or neurologist letter, PMDC verification, patient identifier, dispensing-facility coordination), the DRAP Special Permission for a small-molecule oral product with a clearly documented diagnosis (TD or HD chorea) and a clearly framed local-unavailability statement typically clears in four to eight weeks. The HD chorea indication is newer (FDA approval August 2023) and DRAP reviewers may take longer on the first wave of HD applications as institutional familiarity builds; ten to sixteen weeks is realistic in the upper range. The ambient-shipping profile means logistics adds minimal additional time once the NOC is in hand; standard pharmaceutical air freight to Karachi or Lahore is a 5 to 10 business day window door-to-pharmacy. A realistic end-to-end planning horizon from first contact to in-hand dispensing for a first order is six to fourteen weeks. Quarterly refill cycles follow a shorter cadence once the documentation pattern is established. These ranges are typical, not promises.

## Section 7. What your physician needs to provide

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For tardive dyskinesia, the treating psychiatrist's clinical justification letter ideally documents the causative antipsychotic exposure history (drug, duration, indication for the antipsychotic), the TD diagnosis with reference to the Abnormal Involuntary Movement Scale (AIMS) or comparable clinician-administered assessment, the prior management attempts (dose reduction of the causative agent, antipsychotic switch where clinically feasible), and the rationale for selecting valbenazine. The planned dose schedule is on the application: starting 40 mg once daily; after one week, increase to the recommended dose of 80 mg once daily; 40 mg or 60 mg once daily may be considered for patients who do not tolerate 80 mg or based on response. Doses are taken once daily with or without food. Dose reductions are required for patients on strong CYP3A4 inhibitors, strong CYP2D6 inhibitors, or who are known CYP2D6 poor metabolizers; the maximum recommended dose in these settings is 40 mg once daily.

For chorea associated with Huntington's disease, the treating neurologist's clinical justification letter ideally references the genetic confirmation of HD where available, the chorea severity assessment, the patient's psychiatric status given the FDA boxed warning for depression and suicidality specific to the HD chorea indication, and the planned dose schedule (starting 40 mg once daily; titrating weekly in 20 mg increments based on chorea reduction, tolerability, and

clinical assessment, up to a maximum recommended dose of 80 mg once daily). The HD chorea boxed warning requires that mood and suicidal ideation be assessed at baseline and on an ongoing basis, with caregivers and clinicians both involved; the application should reflect that this assessment is built into the monitoring plan. Other monitorable items across both indications include somnolence, parkinsonism, and QT prolongation in patients with congenital long QT, on QT-prolonging medications, or known CYP2D6 poor metabolizers.

The prescribing physician's PMDC license number is on every document. The dispensing-facility licence sits alongside the letter in the OIES filing. Post-import pharmacovigilance reporting through the DRAP Pharmacovigilance Centre stays with the treating physician for any adverse events. Reserve Meds does not write the clinical letter and does not file with DRAP; we supply the documentation kit, the Neurocrine authenticity attestation, and the chain-of-custody plan.

## **Section 8. Common questions about Ingrezza in Pakistan**

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**Will Adamjee, Jubilee, EFU, or State Life cover this?** Coverage for named-patient imports of unregistered specialty drugs at this price point is uncommon across Pakistani health plans. We supply the documentation an insurer needs to assess a claim; the claim is yours or your hospital's to file. The realistic default is cash-pay.

**How does Sehat Sahulat interact with named-patient imports?** The Rs. 1,000,000 per family per year ceiling is structured around in-network empaneled hospital treatment, not imported drug procurement, and does not cover a sustained Ingrezza maintenance regimen at WAC pricing. Patients can still use Sehat Sahulat for unrelated hospitalisation while Ingrezza is procured separately on cash-pay.

**Will my PMDC-licensed psychiatrist or neurologist's letter be sufficient if DRAP queries the case?** Yes. PMDC-licensed psychiatrists and neurologists at the major tertiary centres have signing authority on Personal Use Import applications. For tardive dyskinesia the psychiatrist signs; for Huntington's chorea the neurologist signs. DRAP may request additional clarification on the diagnosis assessment or on the rationale for valbenazine over the alternative VMAT2 inhibitor; the treating physician answers those queries directly.

**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 original TD label. The most commonly reported adverse reaction across both indications is somnolence. Other notable warnings include QT prolongation, parkinsonism (including hypokinesia and rigidity), and neuroleptic malignant syndrome. The boxed warning is flagged in every patient-facing communication for HD chorea cases and is confirmed acknowledged by the treating neurologist in the Reserve Meds case file.

**What is the monitoring requirement?** Baseline and ongoing assessment of mood, suicidal ideation, and depressive symptoms is required for HD patients, with caregivers and clinicians both involved. Sedation should be monitored, particularly when starting and titrating. QT assessment is appropriate in patients with congenital long QT, on QT-prolonging medications, or known CYP2D6 poor metabolizers. Watch for emergent parkinsonism.

**Why Ingrezza versus deutetrabenazine (Austedo)?** Both are FDA-approved selective VMAT2 inhibitors approved for both TD and HD 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. The decision is clinical and patient-specific, and is the treating psychiatrist's

or neurologist's call. Reserve Meds supports access to either drug through the Personal Use Import pathway.

## Section 9. Where Reserve Meds fits in Ingrezza cases

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Reserve Meds is a US-based concierge coordinator. We do not replace your psychiatrist or neurologist, do not replace DRAP, and do not replace your dispensing hospital pharmacy or the in-country importer. For Ingrezza specifically, the orchestration we provide is US-side sourcing through Neurocrine's specialty-pharmacy channel (this drug is not on open wholesale distribution; the authenticity-attestation work is part of the file), the regulatory documentation kit your psychiatrist or neurologist and the dispensing hospital pharmacy need for the DRAP Personal Use Import filing through OIES, the Neurocrine authenticity attestation tying the consignment back to the legitimate US supply chain, the international ambient air-freight logistics, and a single named coordinator who stays with the family across the first order and the quarterly refill cycles that maintenance therapy generates. For HD chorea cases specifically, the boxed warning for depression and suicidality is flagged in patient-facing materials and confirmed acknowledged by the treating neurologist before the case proceeds. No prior Reserve Meds case experience exists for Ingrezza at the date of this page; standard NPP coordination applies with the specialty-pharmacy-channel sourcing being the distinguishing operational characteristic versus an open-distribution small molecule.

## Section 10. Next step

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If your psychiatrist or neurologist has identified Ingrezza as the appropriate option for tardive dyskinesia or for chorea associated with Huntington's disease and you are based in Pakistan, the next step is the waitlist. We confirm eligibility within 24 to 48 hours, route the conversation to a structured documentation work-up, and align with your dispensing hospital pharmacy or the DRAP-licensed importer on the OIES filing. **Reserved for you.**

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*This guide is informational, not medical or legal advice. The DRAP Personal Use Import framework requires licensed clinical judgment; Reserve Meds is the coordinator, not the prescriber or the dispensing facility.*

**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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