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## Jascayd access in UAE: the EDE named-patient pathway

How patients in the United Arab Emirates access Jascayd (nerandomilast) for idiopathic pulmonary fibrosis and progressive pulmonary fibrosis, an FDA-approved oral anti-fibrotic not yet locally registered.

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

### Quick orientation

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Jascayd is the brand name for nerandomilast, a once-orally-dosed preferential phosphodiesterase 4B inhibitor developed by Boehringer Ingelheim. The US FDA approved Jascayd on 7 October 2025 for the treatment of idiopathic pulmonary fibrosis (IPF) in adults, and in December 2025 for progressive pulmonary fibrosis (PPF) in adults. Jascayd is the first new FDA-approved IPF therapy in more than a decade and the first and only preferential PDE4B inhibitor approved in either indication. As of this review date, Jascayd is not on the United Arab Emirates federal drug register. A UAE-licensed pulmonologist who wants to prescribe it for a specific patient files an unregistered-medicine import permit through the Emirates Drug Establishment (EDE). Reserved for you.

### Why patients in the UAE need Jascayd via a named-patient pathway

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The UAE's regulatory framework is mature, but its registration footprint cannot keep pace with every FDA launch. Jascayd is approved in the United States and China (with NMPA approvals for IPF in 2025 and PPF in December 2025).

Submissions in the European Union, the United Kingdom, and Japan are under review with decisions anticipated in 2026. No UAE local registration is on file as of this review date. For a UAE patient whose IPF or PPF has progressed on or who has been intolerant of nintedanib or pirfenidone, the practical clinical reality is that the third FDA-approved anti-fibrotic mechanism is not commercially reachable through a local pharmacy stocking pattern.

The disease side of that equation matters. IPF carries a median survival of three to five years from diagnosis without effective anti-fibrotic therapy, and PPF carries a similar progressive trajectory. The clinical cost of waiting on local registration is loss of lung function that does not return. UAE patients who have the documentation and the means to coordinate cross-border access reach for Jascayd precisely because the local registration timeline does not match the disease timeline. The EDE pathway exists for exactly this situation.

### The EDE named-patient pathway for Jascayd

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The federal pathway is the unregistered-medicine import permit. The Ministry of Health and Prevention (MOHAP) historically administered the framework, and from 29 December 2025 the Emirates Drug Establishment took over 44 core services under Federal Decree-Law No. 38 of 2024, including marketing authorisations, import and export permits, pharmacovigilance oversight, and personal-use import permits. EDE filings flow through [ede.gov.ae](https://ede.gov.ae). The framework allows licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable.

For a Jascayd submission, the clinical justification letter centres on the IPF or PPF diagnosis and the prior anti-fibrotic history. The letter typically documents the diagnostic workup that established IPF (high-resolution CT pattern, multidisciplinary discussion conclusion, exclusion of other interstitial lung diseases) or established PPF (progressive fibrosing ILD meeting the trial criteria of FVC decline, symptom worsening, or imaging progression on a prior fibrosing ILD diagnosis). It records the use of nintedanib or pirfenidone (drug, dose, duration, FVC trajectory on therapy, reason for discontinuation or addition). It then sets out the clinical rationale for Jascayd: a third mechanism (preferential PDE4B

inhibition) is now FDA-approved, and the trials permitted background nintedanib or pirfenidone so the combination pathway is on label, subject to dose-reduction restrictions when combined with pirfenidone.

The standard EDE application set follows. The treating pulmonologist's UAE medical licence verification is filed (MOHAP, DHA, DOH, or Sharjah Health Authority depending on practice location). The patient identifier is included anonymised where the EDE submission allows. Full product details are listed: brand name Jascayd, generic name nerandomilast, manufacturer Boehringer Ingelheim Pharmaceuticals, Inc., strength (9 mg or 18 mg film-coated tablets), pack size, quantity requested, intended treatment duration. The destination dispensing facility name, licence number, and pharmacy in charge are listed, with a chain-of-custody plan describing how the medicine moves from US specialty wholesale through the UAE importer to the dispensing pharmacy.

Approval timelines for routine cases are typically 5 to 15 business days. Anti-fibrotic prescriptions for IPF and PPF are recognised specialty workflows at UAE tertiary respiratory services, so once the first Jascayd permit has issued for a given institution, repeat filings for the same patient under continuation move quickly.

## **Where Jascayd gets dispensed in the UAE**

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Jascayd is supplied as film-coated oral tablets in two strengths (9 mg and 18 mg). It is room-temperature stable. There is no reconstitution, no refrigeration, no freezing, no cold-chain requirement, and there is no REMS programme at the time of approval. Dispensing therefore does not require infusion infrastructure or specialised cold storage. What it requires is a UAE-licensed dispensing facility with an in-house import pharmacy or a relationship with a specialty importer holding a pharmaceutical establishment licence, and a treating pulmonologist with the ability to monitor anti-fibrotic therapy.

The institutions named in the UAE pathway with respiratory and pulmonary capability include Cleveland Clinic Abu Dhabi, Sheikh Khalifa Medical City (SEHA network), American Hospital Dubai, King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City. All of these maintain pharmaceutical establishment licences and routinely file unregistered-medicine permits. For patients under the care of a private pulmonologist or specialty respiratory practice without internal import infrastructure, the case routes through a Dubai- or Abu Dhabi-based specialty importer that holds the establishment licence, files the EDE permit, and clears customs to a partner outpatient pharmacy. Patients resident in the Northern Emirates typically route to a Dubai or Abu Dhabi centre where the treating pulmonologist holds privileges or co-manages with a UAE-licensed specialist.

## **Real cost picture for Jascayd in the UAE**

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The US list price for Jascayd at launch was reported at approximately USD 16,219.68 per month, which annualises to approximately USD 194,636 per year at the manufacturer-stated list level. For named-patient orders to the UAE, the patient-facing cost picture has three layers: the US specialty wholesale acquisition cost for the prescribed strength and quantity, the international logistics layer, and the regulatory documentation and Reserve Meds coordination layer.

International logistics for an ambient oral tablet typically runs USD 400 to 800 to the UAE, depending on the destination emirate and the urgency window. The UAE dirha