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Jascayd access in Saudi Arabia

The first new IPF therapy in over a decade and the first PDE4B inhibitor approved in pulmonary fibrosis, reached through the SFDA Personal Importation Program.

Quick orientation

Jascayd (nerandomilast) is an oral, preferential PDE4B inhibitor from Boehringer Ingelheim, approved by the US FDA in October 2025 for idiopathic pulmonary fibrosis (IPF) in adults and in December 2025 for progressive pulmonary fibrosis (PPF) in adults. It is the first new FDA-approved therapy for IPF in more than a decade and the first preferential PDE4B inhibitor approved in either indication. In Saudi Arabia, Jascayd is not yet registered with the Saudi Food and Drug Authority (SFDA). For Saudi pulmonology patients who have progressed on or cannot tolerate the two prior anti-fibrotic agents (nintedanib and pirfenidone), and for treating pulmonologists who want a third mechanistic option or an on-label combination partner, the lawful route is the SFDA Personal Importation Program (PIP). Reserve Meds coordinates US specialty pharmacy sourcing, the SFDA documentation kit, and ambient international logistics. Reserved for you.

Why patients in Saudi Arabia need Jascayd via the named-patient pathway

The access gap for Jascayd in the Kingdom has the most common shape: the drug is approved by the US FDA but the manufacturer has not yet completed local SFDA registration. Boehringer Ingelheim has filings under review with the European Medicines Agency, the UK MHRA, and Japan's PMDA with decisions anticipated in 2026, and China's NMPA has already approved both indications. As of this page's review date, none of the Gulf Cooperation Council national authorities, SFDA included, list a local registration for nerandomilast. For Saudi pulmonologists managing IPF or PPF patients today, the local commercial channel does not yet contain the drug.

This gap matters clinically because IPF carries a median survival of three to five years from diagnosis without effective anti-fibrotic therapy, and PPF follows a similarly progressive trajectory. Lung function lost to fibrotic progression does not return. Patients who have already exhausted nintedanib (Ofev, also Boehringer) for tolerability, or who have progressed on or cannot tolerate pirfenidone, need a mechanistically distinct option, and the FIBRONEER trials permitted background nintedanib or pirfenidone, so combination therapy is on label and clinically supported. The SFDA Personal Importation Program is designed for cases of this shape: an FDA-approved drug, a documented clinical need, and a treating physician under their Saudi Commission for Health Specialties license filing for a specific named patient.

The SFDA Personal Importation Program for Jascayd

The SFDA Personal Importation Program allows a KSA-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognized reference authority (the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable. Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector. The agency

increasingly routes named-patient transactions through its Ghad digital platform at ghad.sfda.gov.sa.

For a Jascayd case, the application package contains the clinical justification letter from the treating pulmonologist (IPF or PPF diagnosis with ICD-10 coding, baseline and serial forced vital capacity measurements, prior anti-fibrotic trial history, the requested dose and titration plan, and the monitoring plan), SCFHS license verification, an SFDA-format anonymized patient identifier, product details (Jascayd 9 mg and 18 mg film-coated tablets, Boehringer Ingelheim as manufacturer of record, country of origin, pack size, requested quantity, lot, expiry), the destination dispensing facility license, and a chain-of-custody plan covering US release through international transit. Because Jascayd is ambient-temperature, the chain-of-custody plan does not need to reference cold-chain validation, which is a meaningful operational simplification compared to a refrigerated biologic.

The clinical-justification angle specific to Jascayd is the documented progression on or intolerance of nintedanib or pirfenidone, with reference to the patient's FVC decline trajectory, and (where the clinician is pursuing combination therapy) the rationale for adding a PDE4B inhibitor to background anti-fibrotic therapy. The treating physician's letter typically names the prior anti-fibrotic agents trialed, the documented outcomes (FVC decline, intolerable diarrhea or hepatic enzyme elevation on nintedanib, photosensitivity or GI intolerance on pirfenidone), and the clinical reasoning for moving to a PDE4B mechanism. The dosing plan (18 mg orally twice daily, with reduction to 9 mg twice daily for tolerability except when combined with pirfenidone where the label restricts dose reduction, and reduction to 9 mg twice daily when co-administered with strong CYP3A inhibitors) belongs in the same letter.

Approval timelines for routine cases at an established tertiary center typically run 10 to 21 business days. A first-time importer or a request that triggers SFDA queries on the novel mechanism can extend the timeline to six to ten weeks.

Where Jascayd gets dispensed in Saudi Arabia

Jascayd is a room-temperature oral tablet, which broadens the dispensing-facility shortlist. The institutions that handle SFDA named-patient imports as established workflow and have pulmonology specialty capability include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs network (MNGHA) in Riyadh and Jeddah, King Saud University Medical City (KSUMC), Dr. Sulaiman Al Habib Medical Group (HMG), Saudi German Health, Dr. Soliman Fakeeh Hospital in Jeddah, and Dallah Hospital in Riyadh. KFSH&RC and the academic centers carry interstitial lung disease clinics with serial FVC monitoring infrastructure, which is the natural home for an IPF or PPF patient.

For patients based outside Riyadh and Jeddah, the practical route is to partner with an SFDA-licensed specialty importer in one of those two cities, which handles the SFDA filing and customs clearance. Because Jascayd ships under ambient conditions and does not require temperature loggers or qualified shippers under standard guidance, the multi-leg routings typical of Eastern Province, Madinah, Tabuk, and Asir delivery are operationally straightforward.

Real cost picture for Jascayd in Saudi Arabia

The transparent cost build for a Jascayd case has three line items. First, the underlying US drug cost. Jascayd's US list price at launch is reported at approximately USD 16,219.68 per month, which annualizes to approximately USD 194,636 per year, or roughly SAR 60,824 per month and

SAR 729,885 per year at the 3.75 SAR per 1 USD currency peg. Second, international logistics, which for an ambient-temperature oral product run in the SAR 1,500 to SAR 3,000 range (USD 400 to USD 800) per shipment. The compact dosage form supports 30-day or 90-day fill cadences depending on destination-country import allowance, which can reduce shipment frequency. Third, regulatory documentation handling at the Saudi end and the Reserve Meds coordination fee, quoted as named line items rather than bundled.

On the insurance side, Bupa Arabia, Tawuniya, and MedGulf Arabia handle named-patient imports case-by-case under the Council of Cooperative Health Insurance framework. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately. The Boehringer Ingelheim CareConnect4Me copay and patient-assistance program is US-only and does not extend to Saudi cross-border patients.

Typical timeline for Jascayd in Saudi Arabia

A routine Jascayd case at a tertiary center with established PIP workflow typically clears 10 to 21 business day