

[Skip to main content](#)

[Home](#) / [Drugs](#) / [Jascayd](#) / [In Egypt](#)

## Jascayd access in Egypt

The first new anti-fibrotic in more than a decade for idiopathic pulmonary fibrosis and progressive pulmonary fibrosis, reached through the Egyptian Drug Authority Personal Importation pathway.

### Quick orientation

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Jascayd (nerandomilast) is an oral preferential phosphodiesterase 4B (PDE4B) inhibitor developed by Boehringer Ingelheim. The US FDA approved Jascayd for idiopathic pulmonary fibrosis (IPF) on October 7, 2025 and added a second approval for progressive pulmonary fibrosis (PPF) in December 2025. 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 Egypt, Jascayd is not yet registered with the Egyptian Drug Authority (EDA). For Egyptian patients with IPF or PPF whose pulmonologist has reached the point of considering a third mechanistic option (alongside or after nintedanib or pirfenidone), the lawful route is the EDA Personal Importation pathway, supported by a US specialty pharmacy procurement chain and named-patient documentation prepared in coordination with the dispensing institution. Reserve Meds coordinates the US sourcing, the documentation kit your pulmonologist will need, and the international logistics on the family's behalf, while clinical decisions stay with your treating physician. Reserved for you.

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

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The access gap for Jascayd in Egypt is structural. Jascayd received its first FDA approval in October 2025, and as of this page's review date the Boehringer Ingelheim commercial filing footprint with the EDA Drug Registration Sector is not yet in place. The drug is not on the Egyptian national registration list. 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 delay is loss of lung function that does not return.

The two anti-fibrotics currently used in Egypt are nintedanib (Ofev) and pirfenidone, which are FDA-approved and registered in many international markets. For patients who progress on either, or who do not tolerate them because of gastrointestinal burden, hepatotoxicity, or photosensitivity, the Egyptian formulary has no third mechanistic option available locally. Jascayd is that third option, and the FDA-approved label permits monotherapy or combination with nintedanib or pirfenidone (combination with pirfenidone carries a label restriction on dose reduction). The Egyptian Drug Authority Personal Importation framework, codified by Law No. 151 of 2019, is the lawful route when a recognised reference authority has approved a medicine and no clinically equivalent locally registered alternative is suitable for the named patient.

### The EDA named-patient pathway for Jascayd

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The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, with executive regulations issued under Prime Minister Decision No. 777 of 2020. EDA permits importation of unregistered medicines for a specific named patient where no equivalent registered product is available locally or where the available quantity of an equivalent locally registered product cannot meet the patient's clinical need. The pathway is commonly referred to as Personal

Importation and described in EDA correspondence as Special Access or Compassionate Use for novel agents.

For a Jascayd case, applications are filed through the dispensing institution's import pharmacy. The standard package includes the clinical justification letter from the treating pulmonologist on hospital letterhead (the IPF or PPF diagnosis with the supporting high-resolution CT, lung function testing, and where applicable the multidisciplinary discussion record; prior anti-fibrotic trials with named medicines and documented outcomes; the clinical rationale for Jascayd as monotherapy or as combination therapy; the requested dose and duration), a recent prescription specifying brand name (Jascayd), generic name (nerandomilast), strength (9 mg or 18 mg), dosage form, and quantity, the patient identifier copy (national ID card or passport), the treating pulmonologist's Egyptian Medical Syndicate membership number and Ministry of Health licence reference, product details (Boehringer Ingelheim Pharmaceuticals, Inc. as manufacturer of record, country of origin, FDA approval reference, shelf life, room-temperature storage), the destination dispensing facility licence, and a chain-of-custody plan covering transit to the receiving Egyptian pharmacy through Cairo International Airport.

The clinical-justification angle specific to Jascayd is anti-fibrotic line documentation. The treating pulmonologist's letter typically names the prior anti-fibrotics trialed (nintedanib, pirfenidone, or both), the outcomes observed (continued FVC decline, intolerable diarrhea or hepatotoxicity, photosensitivity dermatitis on pirfenidone), and the clinical reasoning for adding the PDE4B mechanism or substituting for an intolerated incumbent. Where combination with nintedanib or pirfenidone is planned, the letter states this explicitly with reference to the FIBRONEER trial design and the label provisions. The dosing plan (target maintenance 18 mg twice daily approximately twelve hours apart with or without food, with step-down to 9 mg twice daily for tolerability except where pirfenidone is co-administered, and 9 mg twice daily where a strong CYP3A inhibitor is on board) and the monitoring plan (FVC at the standard pulmonologist cadence, GI tolerability, LFTs at the pulmonologist's discretion) belong in the same letter.

Routine EDA personal-import authorisations for well-documented respiratory cases typically process in a 3 to 6 week window once a complete package is submitted, though this range varies by case complexity. A first preferential PDE4B inhibitor case at a given institution may take longer because the reviewer has not previously seen the mechanism. EDA reserves discretion at every step. Reserve Meds does not promise EDA timelines and is not the filer.

## **Where Jascayd gets dispensed in Egypt**

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Jascayd is a room-temperature oral tablet, which broadens the dispensing-facility shortlist relative to a cold-chain biologic. The institutions that handle EDA named-patient imports as routine workflow and have specialty pulmonology capability include Cairo University Hospitals (Kasr Al Ainy) with its Drug Information Center and dedicated chest and pulmonology services, Ain Shams University Hospitals, Dar Al Fouad Hospital in 6th of October City (JCI-accredited, with active pulmonology and internal medicine services as part of the Alameda Healthcare Group), As-Salam International Hospital in Cairo, and the Cleopatra Hospitals Group with its multi-site pulmonology infrastructure. The Magdi Yacoub Heart Foundation has import experience for pulmonary hypertension therapies and is relevant where IPF coexists with pulmonary hypertension under joint cardiology-pulmonology care.

For patients whose treating pulmonologist is at a regional hospital outside Cairo, Giza, or Alexandria, the practical route is to partner with a Cairo-based licensed specialty importer that handles the EDA filing and customs clearance through Cairo International Airport, with final delivery to a licensed dispensing facility. The importer holds the dispensing pharmacy licence;

the clinical justification letter still originates with the treating pulmonologist. Because Jascayd tablets are room-temperature stable, the operational burden lives at customs documentation and EDA registration evidence rather than at cold-chain control.

## **Real cost picture for Jascayd in Egypt**

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Reserve Meds quotes Egyptian cases in USD and accepts USD wire transfers. The transparent cost build for a Jascayd case has three line items. First, the underlying US drug cost. Jascayd's US list price