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# Jascayd access in India: the CDSCO Rule 36 named-patient pathway

How adults in India living with idiopathic pulmonary fibrosis or progressive pulmonary fibrosis legally obtain Jascayd (nerandomilast) from US-source supply, including combination use with nintedanib or pirfenidone on label.

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

## Quick orientation

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Jascayd (nerandomilast) is a preferential phosphodiesterase 4B (PDE4B) inhibitor developed by Boehringer Ingelheim. The US Food and Drug Administration approved Jascayd on 7 October 2025 for idiopathic pulmonary fibrosis (IPF) in adults and on 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. Jascayd may be used as monotherapy or, where clinically appropriate, in combination with nintedanib (Ofev) or pirfenidone per label guidance. There is no public record of Jascayd registration with the Central Drugs Standard Control Organization (CDSCO) as of this review. Indian patients reach the medicine through the CDSCO personal importation framework under Rule 36 of the Drugs and Cosmetics Rules 1945, with Form 12A application and Form 12B permit issued by the Drugs Controller General of India (DCGI). Reserve Meds coordinates US specialty-pharmacy sourcing, ambient international logistics, and the documentation kit your pulmonologist needs to file.

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

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India has a deep interstitial-lung-disease network. The Department of Pulmonary Medicine at AIIMS New Delhi handles complex IPF and PPF cases. PD Hinduja Hospital Mumbai, Postgraduate Institute of Medical Education and Research (PGIMER) Chandigarh, Christian Medical College (CMC) Vellore, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis Memorial Research Institute Gurgaon, Medanta The Medicity Gurgaon, Kokilaben Mumbai, MGM Chennai, and Manipal Bangalore round out the tertiary pulmonology tier. Nintedanib (Ofev, also Boehringer Ingelheim) is locally registered and available in India for IPF and PPF; pirfenidone is widely available through multiple Indian generic manufacturers. What is missing is a third mechanism. Patients who progress on or cannot tolerate the incumbents have, until 2025, had no on-mechanism on-label option in India. Jascayd is not yet locally registered with CDSCO; personal importation under Rule 36 is the legal route.

Disease urgency matters here. IPF carries a median survival of three to five years from diagnosis without effective anti-fibrotic therapy; PPF carries a similar progressive trajectory. The clinical cost of treatment delay is loss of lung function that does not return. Indian families who have watched a parent or spouse decline on nintedanib or pirfenidone, particularly when intolerance is the issue rather than failed response, reach for Jascayd precisely because the local registration

timeline (EMA, UK MHRA, and PMDA decisions anticipated in 2026; CDSCO timeline not yet published) is not aligned with the patient's disease timeline.

## **The CDSCO Rule 36 named-patient pathway for Jascayd**

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The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits the import of a small quantity of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the DCGI at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's National Medical Commission (NMC) registration number and the quantity required for treatment. The quantity of any single drug imported is capped at one hundred average doses per application, which for Jascayd at twice-daily dosing fits a 50-day supply per filing.

For institutional Compassionate Use of drugs not approved for marketing in India at all, the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a life-threatening condition. IPF and PPF fit the life-threatening condition framing precisely given the median survival data.

For Jascayd specifically, the clinical-justification angle in the Form 12A filing is the prior-line history and the combination intent if applicable. The strongest applications consistently document: a confirmed diagnosis of idiopathic pulmonary fibrosis or progressive pulmonary fibrosis with the diagnostic basis (high-resolution CT pattern, multidisciplinary discussion conclusion, lung biopsy where performed); baseline forced vital capacity (FVC) and the FVC trajectory over the preceding six to twelve months; the prior anti-fibrotic history specifically (nintedanib trial with dates, dose, response, tolerability; pirfenidone trial with the same elements); the specific clinical rationale for adding or switching to Jascayd (intolerance to nintedanib's GI burden, ongoing FVC decline on the incumbent, or the intent to combine for additive anti-fibrotic effect); the proposed dosing plan following the FDA-labeled schedule (target maintenance dose 18 mg by mouth twice daily approximately 12 hours apart, with or without food; dose reduction to 9 mg twice daily for tolerability except in patients concomitantly receiving pirfenidone where the label restricts dose reduction; reduction to 9 mg twice daily with concomitant strong CYP3A inhibitors; avoidance with moderate or strong CYP3A inducers); and the monitoring plan including GI tolerability assessment, liver function tests per pulmonologist discretion, and serial pulmonary function testing primarily FVC. CDSCO's published guidance states Form 12B is typically issued within one to two business days for routine applications where the documentation is complete.

## **Where Jascayd gets dispensed in India**

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Jascayd is a film-coated oral tablet taken twice daily. Tablets may be swallowed whole or dispersed in water per the prescribing information, which is useful for older patients with swallowing difficulty. The product does not require infusion infrastructure, an oxygen-suite handoff, or specialised dispensing equipment beyond what a tertiary respiratory clinic already provides. The dispensing facility must hold a valid drug licence. Typical dispensing points include the hospital pharmacy at AIIMS New Delhi, PGIMER Chandigarh, PD Hinduja Mumbai, CMC Vellore, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata), Fortis

Memorial Research Institute Gurgaon and Mulund Mumbai, Medanta The Medicity Gurgaon, Kokilaben Dhirubhai Ambani Hospital Mumbai, MGM Healthcare Chennai, and Manipal Hospitals Bangalore. Where the treating pulmonologist is in a smaller city, the practical pattern is to route through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore.

Because IPF and PPF are chronic conditions and Jascayd is intended for indefinite maintenance, supply continuity is mission-critical. Interruption of an anti-fibrotic is associated with loss of accrued lung-function benefit, so the dispensing rhythm aligns to 30-day or 90-day fills with a re-supply trigger set ahead of the on-hand exhaustion date.

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

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Costs sit in Indian rupees with the rupee floating against the US dollar. In May 2026 the USD/INR rate is in the 94 to 95 range. The US list price for Jascayd at launch is approximately USD 16,219.68 per month, which annualises to approximately USD 194,636 per year at the manufacturer-stated list price. At the prevailing USD/INR rate, the published US list price converts to approximately INR 15.3 lakh per 30-day supply or INR 1.83 crore per year, before any international logistics, documentation, or coordination is layered on. Jascayd is ambient-stable oral tablets, which is the most favourable international-logistics profile: no refrigeration, no gel packs or temperature loggers, and customs documentation does not need to reference cold-chain validation. International shipping to an Indian destination typically runs USD 200 to 600 per shipment (approximately INR 19,000 to 56,000), depending on city and consolidation.

CDSCO permit fees are nominal. India's Union Budget 2026-27 customs-duty rules apply at the HSN-code level confirmed at the documentation stage. GST on most life-saving medicines is 5 percent. None of the major Indian private insurers (Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, Niva Bupa) reimburse a Rule 36 personal import of an unregistered anti-fibrotic as a standard line item. CGHS may consider life-saving non-formulary medicines case by case under the Special DG (DGHS) Expert Committee route, with stricter constraints on drugs not approved by DCGI. The Boehringer "CareConnect4Me" US patient support program (copay assistance, free-trial offers, foundation-grant partnerships) is US-only and does not extend to international named-patient orders. Cash-pay is the operating default.

## **Typical timeline for Jascayd in India**

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For a routine Jascayd case at an established pulmonology institution, the CDSCO Form 12B permit window is typically one to two business days from a complete Form 12A filing, per the regulator's published guidance. Because Jascayd is room-temperature stable, the international transit window is the favourable ambient-cargo range (typically three to five business days from US specialty pharmacy dispatch to Indian customs clearance, depending on the destination port and the day of week). There is no temperature-monitored handoff and no validated cold-chain shipper to coordinate. The bulk of elapsed time sits in upstream documentation assembly and US specialty-pharmacy intake. End-to-end, families typically plan for two to four weeks from pulmonologist decision to first dispensed bottle. For a chronic anti-fibrotic, the more important operational variable is the maintenance refill rhythm, with Reserve Meds re-quoting and re-filing on a 30-day or 90-day cadence aligned to the family's preferred international shipment cycle.

## **What your physician needs to provide**

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The clinical justification letter is the cornerstone of the Form 12A filing. For Jascayd, the strongest letters consistently include: a confirmed diagnosis of IPF or PPF with the diagnostic

basis (high-resolution CT pattern, multidisciplinary discussion conclusion, lung biopsy where performed); baseline FVC and the FVC trajectory over the preceding six to twelve months; the prior anti-fibrotic history (nintedanib trial with dates, dose ranges, response, tolerability and the specific reason for discontinuation or unsatisfactory response; pirfenidone trial with the same elements where applicable); the specific clinical rationale for Jascayd (intolerance to the incumbent, ongoing FVC decline despite the incumbent, or the intent to combine on label for additive anti-fibrotic effect with nintedanib or pirfenidone, with the relevant dose-reduction restriction noted where pirfenidone is the partner); the proposed dosing plan following the FDA-labeled schedule (target maintenance 18 mg twice daily, dose reduction to 9 mg twice daily for tolerability subject to the pirfenidone restriction, CYP3A interaction-driven adjustments); the monitoring plan covering GI tolerability assessment (diarrhoea is the most common adverse event, observed in approximately 41 percent of patients on 18 mg twice daily in the FIBRONEER program), liver function tests per pulmonologist discretion, and serial FVC measurements on the standard IPF or PPF cadence; and the prescribing pulmonologist's NMC registration number.

The patient identifier, the dispensing institution's drug licence, and the chain-of-custody plan from the US specialty pharmacy to the Indian dispensing pharmacy complete the file. The treating pulmonologist retains the clinical decision and the Pharmacovigilance Programme of India (PvPI) adverse-event reporting obligation. Reserve Meds includes the PvPI reference in the documentation kit.

## **Common questions about Jascayd in India**

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### **Can Jascayd be combined with nintedanib?**

Yes. The FIBRONEER trials permitted background nintedanib, and the combination is on label. Combination with pirfenidone is also permitted but with a label-specified restriction on Jascayd dose reduction when pirfenidone is the partner. The treating pulmonologist owns the decision to combine or switch.

### **Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Jascayd?**

Each plan handles named-patient imports case by case. None of the major Indian private insurers reimburse a Rule 36 personal import of an unregistered anti-fibrotic as a standard line item. Where the same insurer is reimbursing locally available nintedanib or pirfenidone for the same patient, the Jascayd line is typically not a covered substitute. Reserve Meds provides itemised documentation that lets the insurer evaluate. Cash-pay is the operating default.

### **What is the safety profile we should be aware of?**

The most common adverse event in the FIBRONEER program was diarrhoea, reported in approximately 41 percent of patients on 18 mg twice daily and 31 percent on 9 mg twice daily, compared with approximately 16 percent on placebo. Diarrhoea is a known PDE4 class effect, and the B-subtype preference is intended to reduce, though not eliminate, the GI burden seen with non-selective PDE4 inhibitors. Permanent discontinuation rates in the trials were similar between Jascayd and placebo arms. The treating pulmonologist reviews the full label with the patient before initiating therapy.

### **Why this drug versus continuing on nintedanib or pirfenidone?**

Mechanism differs. Jascayd is a preferential PDE4B inhibitor; nintedanib is a tyrosine kinase inhibitor; pirfenidone has multi-pathway action. Patients who progress on or cannot tolerate the

incumbents have a third mechanistic option. The pulmonologist owns the decision based on FVC trajectory, tolerability of the current regimen, and the option to combine where clinically appropriate.

### **What is the typical course duration?**

Indefinite. Both IPF and PPF are chronic, progressive interstitial lung diseases. Jascayd is intended as ongoing maintenance therapy taken indefinitely while clinical benefit and tolerability persist. There is no defined stop date in the label.

### **Is Jascayd a controlled substance?**

No. Jascayd is not a DEA-scheduled drug and is in scope for Reserve Meds personal-importation coordination.

### **Where Reserve Meds fits in Jascayd cases**

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Reserve Meds is a US-based concierge coordinator. We do not replace your pulmonologist, do not replace CDSCO or the DCGI, and do not replace the dispensing hospital pharmacy or the licensed specialty importer. What we do is orchestrate US specialty-pharmacy sourcing under DSCSA-compliant serialisation, ambient international logistics, and the documentation kit your pulmonologist needs for the Form 12A filing including the combination-use language where clinically applicable. Jascayd is operationally favourable for international coordination: small molecule, room-temperature, oral, no REMS, no cold-chain, dispersible in water for patients with swallowing difficulty. A single named coordinator carries the case from intake through the titration window and into the indefinite maintenance cadence, with re-supply timing managed to avoid any anti-fibrotic interruption. No prior Reserve Meds closed case experience exists for Jascayd in India as of this review; standard NPP coordination applies, with particular attention to maintenance-supply continuity given the chronic-disease setting.

### **Next step**

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If an adult patient in India has IPF or PPF and the treating pulmonologist is considering Jascayd as monotherapy or in combination with nintedanib or pirfenidone, add the case to the waitlist. We will respond within 24 to 48 hours with a documentation kit for your pulmonologist and an indicative cost range.

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