



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 May 2026  
EMADOC-1829012207-48872  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Jascayd nerandomilast

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Jascayd, intended for the treatment of adults with idiopathic pulmonary fibrosis (IPF) or adults with progressive pulmonary fibrosis (PPF).

The applicant for this medicinal product is Boehringer Ingelheim International GmbH.

Jascayd will be available as 9 mg and 18 mg film-coated tablets. The active substance of Jascayd is nerandomilast, an immunosuppressant (ATC code: L04AA61). Nerandomilast is a selective inhibitor of phosphodiesterase 4 (PDE4) with anti-fibrotic and immunomodulatory effects. It therefore reduces the expression of pro-fibrotic growth factors and inflammatory cytokines, which are overexpressed in fibrotic lung disease.

The benefit of Jascayd is a statistically significant and clinically relevant decrease in the rate of forced vital capacity (FVC) decline compared with placebo for both 18 mg and 9 mg twice daily dosing.

In the IPF population, at Week 52 the adjusted mean change from baseline in FVC versus placebo was 81.1 ml (95% CI: 46.0, 116.3;  $p < 0.0001$ ) with nerandomilast 9 mg and 67.2 ml (95% CI: 31.9, 102.5;  $p = 0.0002$ ) with nerandomilast 18 mg. The adjusted mean decline in FVC was -115 ml with 18 mg and -139 ml with 9 mg compared with -183 ml with placebo.

In the PPF population, the adjusted mean decline in FVC was -99 ml with nerandomilast 18 mg and -85 ml with nerandomilast 9 mg compared with -166 ml with placebo.

The most common side effect with Jascayd is diarrhoea.

The full indication is:

Jascayd is indicated for the treatment of adult patients with Idiopathic Pulmonary Fibrosis.

Jascayd is indicated for the treatment of adult patients with Progressive Pulmonary Fibrosis.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



The treatment should be initiated by physicians experienced in the management of diseases for which Jascayd is approved.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.