EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2025
EMA/CHMP/156564/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nintedanib Viatris

nintedanib

On 19 June 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nintedanib Viatris, intended for the treatment of adults with idiopathic pulmonary fibrosis (IPF), adults and children aged 6 years and above with other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype, and adults and children aged 6 years and older with systemic sclerosis associated interstitial lung disease (SSc-ILD).

The applicant for this medicinal product is Viatris Limited.

Nintedanib Viatris will be available as 100 mg and 150 mg soft capsules. The active substance of Nintedanib Viatris is nintedanib, a protein kinase inhibitor (ATC code: L01EX09). By binding to several protein kinases, nintedanib inhibits intracellular signalling cascades involved in the pathogenesis of fibrotic tissue remodelling in interstitial lung diseases.

Nintedanib Viatris is a generic of Ofev, which has been authorised in the EU since 14 January 2015. Studies have demonstrated the satisfactory quality of Nintedanib Viatris, and its bioequivalence to the reference product Ofev. A question and answer document on generic medicines can be found here.

The full indication is:

> Nintedanib Viatris is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
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> Nintedanib Viatris is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see section 5.1).
>
> Nintedanib Viatris is indicated in children and adolescents from 6 to 17 years old for the treatment of clinically significant, progressive fibrosing interstitial lung diseases (ILDs) (see section 4.2 and 5.1).
>
> Nintedanib Viatris is indicated in adults, adolescents and children aged 6 years and older for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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For adults, treatment with Nintedanib Viatris should be initiated by physicians experienced in the in the management of diseases for which nintedanib is approved.

For children, treatment with Nintedanib Viatris should be initiated only after involvement of a multidisciplinary team (physicians, radiologists, pathologists) experienced in the diagnosis and treatment of ILDs.

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.