10 November 2022
EMA/CHMP/846957/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pirfenidone Viatris

pirfenidone

On 10 November 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pirfenidone Viatris, intended for the treatment of idiopathic pulmonary fibrosis (IPF). The applicant for this medicinal product is Viatris Limited.

Pirfenidone Viatris will be available as 267 mg, 534 mg and 801 mg film-coated tablets. The active substance of Pirfenidone Viatris is pirfenidone, an immunosuppressant (ATC code: L04AX05). Its mechanism of action has not been fully established, but existing data suggest that pirfenidone exerts both antifibrotic and anti-inflammatory properties.

Pirfenidone Viatris is a generic of Esbriet, which has been authorised in the EU since 2 March 2011. Studies have demonstrated the satisfactory quality of Pirfenidone Viatris, and its bioequivalence to the reference product Esbriet. A question and answer document on generic medicines can be found here.

The full indication is:

> Pirfenidone is indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

Pirfenidone Viatris should be prescribed by physicians experienced in the diagnosis and treatment of IPF.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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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