22 April 2022
EMA/CHMP/215096/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pirfenidone AET

pirfenidone

On 22 April 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 AET, intended for the treatment of idiopathic pulmonary fibrosis (IPF). The applicant for this medicinal product is Alfred E. Tiefenbacher (GmbH & Co. KG).

Pirfenidone AET will be available as film-coated tablets. The active substance of Pirfenidone AET 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 AET is a generic of Esbriet, which has been authorised in the EU since 2 March 2011. Studies have demonstrated the satisfactory quality of Pirfenidone AET 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 AET is indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

Pirfenidone AET 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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