23 February 2023
EMA/CHMP/64403/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Esbriet

pirfenidone

On 23 February 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Esbriet. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted a change to the existing indication to include treatment of 'advanced' idiopathic pulmonary fibrosis (IPF). For information, the full indication for Esbriet will be as follows:[2]

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

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] Removed text as strikethrough

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