27 February 2020
EMA/CHMP/102818/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ofev

nintedanib

On 27 February 2020, 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 Ofev. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new indication as follows:

> "Ofev is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease."

For information, the full indications for Ofev will be as follows:

> "Ofev is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
>
> "Ofev is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease."

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

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