27 February 2025
EMA/CHMP/62074/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Kaftrio

ivacaftor / tezacaftor / elexacaftor

On 27 February 2025, 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 Kaftrio. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Ireland) Limited.

The CHMP adopted extensions to the existing indications for Kaftrio film-coated tablets and granules in sachets to extend their use to patients with at least one non-class I *CFTR* mutation. The full indications for Kaftrio will therefore be as follows:[2]

> Kaftrio tablets are indicated in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one **non-class I** ~~*F508del*~~ mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene (see section**s 4.2 and** 5.1).
>
> Kaftrio granules are indicated in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in paediatric patients aged 2 to less than 6 years who have at least one **non-class I** ~~*F508del*~~ mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene (see section**s 4.2 and** 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website 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] New text in bold, removed text as strikethrough

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