



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2023
EMA/344229/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Kaftrio

ivacaftor / tezacaftor / elexacaftor

On 14 September 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 Kaftrio. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Ireland) Limited.

The CHMP recommended the approval of two new presentations of Kaftrio (60mg/40mg/80mg and 75mg/50mg/100mg granules in sachet) for use in children aged 2 to 5 years of age.

For information, the indication for Kaftrio granules will be as follows:

Kaftrio granules are indicated in a combination regimen with ivacaftor for the treatment of cystic fibrosis (CF) in patients aged 2 to less than 6 years who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene.

For information, the indication for Kaftrio tablets remains unchanged and is provided in the summary of product characteristics (SmPC).

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

