26 April 2023
EMA/CHMP/177745/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orkambi

lumacaftor / ivacaftor

On 26 April 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 Orkambi. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Ireland) Limited.

The CHMP recommended the approval of a new presentation of Orkambi (75mg/94mg granules in sachet) and an extension to the existing indication to allow use in children from 1 year of age.

For information, the full indication for Orkambi will be as follows[2]:

> Orkambi granules are indicated for the treatment of cystic fibrosis (CF) in patients aged **1** ~~2~~ year~~s~~ and older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (see sections 4.2, 4.4, 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 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] New text in **bold,** removed text as ~~strikethrough~~

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