



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 March 2021
EMA/CHMP/153342/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Kaftrio

ivacaftor / tezacaftor / elexacaftor

On 25 March 2021, 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 an extension to the existing indication to extend the use in all patients with at least one F508del mutation.

For information, the full indication for Kaftrio will be as follows: ²

Kaftrio is indicated in a combination regimen with ivacaftor 150 mg tablets for the treatment of cystic fibrosis in patients aged 12 years and older who ~~are homozygous for the~~ **have at least one F508del** mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene ~~or heterozygous for F508del in the CFTR gene with a minimal function (MF) mutation.~~

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 ~~striketrough~~

