



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 September 2020  
EMA/487752/2020  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Symkevi

tezacaftor / ivacaftor

On 17 September 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 Symkevi. The marketing authorisation holder for this medicinal product is Vertex Pharmaceuticals (Ireland) Limited.

The CHMP recommended the approval of a new 50/75-mg strength for Symkevi tablets and an extension to the existing indication to allow use in children from 6 years of age. The full indication will now be as follows:<sup>2</sup>

Symkevi is indicated in a combination regimen with ivacaftor ~~150 mg~~ tablets for the treatment of patients with cystic fibrosis (CF) aged **6** ~~12~~ years and older who are homozygous for the *F508del* mutation or who are heterozygous for the *F508del* mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene: *P67L*, *R117C*, *L206W*, *R352Q*, *A455E*, *D579G*, *711+3A→G*, *S945L*, *S977F*, *R1070W*, *D1152H*, *2789+5G→A*, *3272-26A→G*, and *3849+10kbC→T*.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in **bold**, removed text as ~~strikethrough~~

