22 July 2021
EMA/CHMP/229665/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Vosevi

sofosbuvir / velpatasvir / voxilaprevir

On 22 July 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 Vosevi. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted an extension to the indication for Vosevi as follows:[2]

> Vosevi is indicated for the treatment of chronic hepatitis C virus (HCV) infection in ~~adults~~ **patients aged 12 years and older and weighing at least 30 kg**.

The CHMP also recommended the addition of a new 200/50/50 mg strength for the film-coated tablets.

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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