31 January 2019
EMA/CHMP/901868/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Maviret

glecaprevir / pibrentasvir

On 31 January 2019, 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 Maviret. The marketing authorisation holder for this medicinal product is AbbVie Deutschland GmbH & Co. KG.

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

Maviret is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults **and in adolescents aged 12 to <18 years** (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

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