30 April 2020
EMA/CHMP/54435/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Harvoni

ledipasvir / sofosbuvir

On 30 April 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 Harvoni. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

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

> Harvoni is indicated for the treatment of chronic hepatitis C (CHC) in adult and **paediatric patients** ~~in adolescents~~ aged **3**~~12 to <18~~ years **and above.**

The CHMP also recommended the addition of a new 45 mg/200 mg strength for the film-coated tablets and the introduction of a new pharmaceutical form, coated granules, which will be available in two strengths: 33.75 mg/150 mg and 45 mg/200 mg.

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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