26 May 2016
EMA/CHMP/323098/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Epclusa

sofosbuvir / velpatasvir

On 26 May 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Epclusa, intended for the treatment of chronic hepatitis C in adults. The applicant for this medicinal product is Gilead Sciences International Ltd.

Epclusa is a fixed dose combination of two direct-acting antivirals, sofosbuvir and velpatasvir. It will be available as film-coated tablets (containing 400 mg sofosbuvir and 100 mg velpatasvir). The active metabolite of sofosbuvir is an inhibitor of the hepatitis C virus (HCV) NS5B RNA polymerase, while velpatasvir targets the NS5A protein of the virus.

The benefit with Epclusa when used with or without ribavirin is its very high efficacy against all HCV genotypes including in patients with decompensated cirrhosis. The most common side effects are fatigue, headache and nausea.

The full indication is: "Epclusa is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults (see sections 4.2, 4.4 and 5.1)." It is proposed that Epclusa be prescribed by physicians experienced in the management of patients with HCV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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