22 June 2017
EMA/364961/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Maviret

glecaprevir / pibrentasvir

On 22 June 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Maviret, intended for the treatment of chronic hepatitis C virus (HCV) infection. Maviret was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is AbbVie Ltd.

Maviret is a fixed dose combination (FDC) of two direct acting-antivirals (DAA), glecaprevir and pibrentasvir (ATC code not yet assigned). It will be available as film-coated tablets containing 100 mg glecaprevir and 40 mg pibrentasvir. Glecaprevir is an inhibitor of the HCV NS3/4A protease, while pibrentasvir is an inhibitor of the HCV NS5A protein. Both proteins are essential for HCV replication.

The benefits with Maviret are that it is highly effective against all genotypes of HCV and can be used in patients with severe renal impairment, including in those on dialysis.

The most common side effects are headache and fatigue.

The full indication is: "Maviret is indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults".

It is proposed that Maviret be prescribed by physicians experienced in the management of patients with chronic hepatitis C.

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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