26 April 2019
EMA/CHMP/213099/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dovato

dolutegravir / lamivudine

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dovato, intended for the treatment of HIV infection. The applicant for this medicinal product is ViiV Healthcare B.V.

Dovato is a fixed dose combination of dolutegravir and lamivudine (ATC code: J05AR). It will be available as film-coated tablets (containing 50 mg dolutegravir and 300 mg lamivudine). Dolutegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for HIV replication. Lamivudine is a substrate and competitive inhibitor of HIV reverse transcriptase. After phosphorylation, it is incorporated into the viral DNA chain, resulting in chain termination.

The benefits with Dovato are its ability to inhibit viral replication to a similar extent to standard triple therapy using a single pill regimen. The most common possibly treatment-related side effects are nausea, headache, insomnia and diarrhoea.

The full indication is: "Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine."

It is proposed that Dovato be prescribed by physicians experienced in the treatment of HIV disease.

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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