20 July 2017
EMA/CHMP/275743/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Entecavir Mylan

entecavir

On 20 July 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 Entecavir Mylan, intended for the treatment of chronic hepatitis B. The applicant for this medicinal product is Mylan S.A.S.

Entecavir Mylan will be available as 0.5 mg and 1 mg film-coated tablets. The active substance of Entecavir Mylan is entecavir, an antiviral (ATC code: J05AF10). Entecavir is a nucleoside analogue that blocks an enzyme of the hepatitis B virus, DNA polymerase, and prevents the virus from multiplying and spreading.

Entecavir Mylan is a generic of Baraclude, which has been authorised in the EU since 26 June 2006. Studies have demonstrated the satisfactory quality of Entecavir Mylan, and its bioequivalence to the reference product Baraclude. A question and answer document on generic medicines can be found here.

The full indication is:

"Entecavir Mylan is indicated for the treatment of chronic hepatitis B virus (HBV) infection (see section 5.1) in adults with:

- compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.
- decompensated liver disease (see section 4.4).

For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside-naive patients with HBeAg positive and HBeAg negative HBV infection. With respect to patients with lamivudine-refractory hepatitis B, see sections 4.2, 4.4 and 5.1.

Entecavir Mylan is also indicated for the treatment of chronic HBV infection in nucleoside-naive paediatric patients from 2 to <18 years of age with compensated liver disease who have evidence of active viral replication and persistently elevated serum ALT levels, or histological evidence of

[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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moderate to severe inflammation and/or fibrosis. With respect to the decision to initiate treatment in paediatric patients, see sections 4.2, 4.4, and 5.1."

It is proposed that Entecavir Mylan be prescribed by physicians experienced in the management of chronic hepatitis B 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.