



28 May 2020
EMA/CHMP/270357/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Hepcludex

bulevirtide

On 28 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional² marketing authorisation for the medicinal product Hepcludex³, intended for the treatment of chronic hepatitis delta virus (HDV) infection in adult patients with compensated liver disease. The applicant for this medicinal product is MYR GmbH.

Hepcludex will be available as a 2 mg powder for solution for injection. The active substance of Hepcludex is bulevirtide, an antiviral for systemic use (ATC code: J05AX28). Bulevirtide blocks the entry of hepatitis B virus (HBV) and HDV into hepatocytes by binding to and inactivating NTCP, a bile salt liver transporter that serves as an essential HBV/HDV entry receptor.

The benefit with Hepcludex is its ability to effectively reduce HDV RNA levels and signs of liver inflammation in treated patients. The most common side effects are increases in bile salts, injection site reactions and exacerbation of hepatitis after discontinuation of bulevirtide.

The full indication is:

Hepcludex is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult patients with compensated liver disease.

It is proposed that Hepcludex be prescribed by physicians experienced in the treatment of patients with HDV 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

² A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

³ This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

