



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2024
EMA/CHMP/447783/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Hepcludex bulevirtide

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Hepcludex. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted an extension to the existing indication to include children aged 3 years and older weighing at least 10 kg. For information, the full indication will be as follows:²

Hepcludex is indicated for the treatment of chronic hepatitis delta virus (HDV) infection in plasma (or serum) HDV-RNA positive adult **and paediatric patients 3 years of age and older weighing at least 10 kg** with compensated liver disease.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to 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 New text in bold

