21 April 2017
EMA/CHMP/253159/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ucedane

carglumic acid

On 21 April 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 Ucedane, intended for the treatment of hyperammonaemia due to N-acetylglutamate synthase primary deficiency. The applicant for this medicinal product is Lucane Pharma.

Ucedane will be available as 200-mg dispersible tablets. The active substance of Ucedane is carglumic acid, an amino acid derivative (ATC code: A16AA05). It is a structural analogue of N-acetylglutamate and can replace it in patients who cannot synthesise the compound properly due to a deficiency in the enzyme responsible for its synthesis (N-acetylglutamate synthase).

Ucedane is a generic of Carbaglu, which has been authorised in the EU since 24 January 2003. Studies have demonstrated the satisfactory quality of Ucedane, and its bioequivalence to the reference product Carbaglu. A question and answer document on generic medicines can be found here.

The full indication is:

"Treatment of hyperammonaemia due to N-acetylglutamate synthase primary deficiency."

It is proposed that Ucedane be prescribed by physicians experienced in the treatment of metabolic disorders.

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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