29 May 2019
EMA/290870/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cufence

trientine dihydrochloride

On 29 May 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 Cufence, intended for the treatment of Wilson's disease. Cufence was designated as an orphan medicinal product on 24 October 2003. The applicant for this medicinal product is Univar BV.

Cufence will be available as 200 mg hard capsules (trientine base). The active substance of Cufence is trientine dihydrochloride, a copper-chelating agent (ATC code: A16AX) that removes copper from the body by forming a stable complex that is then eliminated through urinary excretion. Trientine may also inhibit copper absorption from the intestinal tract.

The benefits with Cufence are its ability to decrease the excessively high serum and tissue copper levels in patients with Wilson's disease, which lead to neurological abnormalities and hepatic dysfunction. The most common side effects of Cufence are nausea and occasionally skin rash. Neurological deterioration can occur at the start of the treatment.

The full indication is: "Cufence is indicated for the treatment of Wilson's disease in patients intolerant to D-penicillamine therapy, in adults, adolescents and children aged 5 years or older."

It is proposed that Cufence be initiated by specialist physicians with experience in the management of Wilson's 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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