



21 April 2017  
EMA/CHMP/665612/2017  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Cuprior

#### trientine tetrahydrochloride

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 Cuprior, intended for the treatment of Wilson's disease. Cuprior was designated as an orphan medicinal product on 19 March 2015. The applicant for this medicinal product is gmp-orphan SA.

Cuprior will be available as 150 mg tablets (trientine base). The active substance of Cuprior is trientine tetrahydrochloride. Trientine is 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 Cuprior are its ability to decrease serum copper levels in patients with Wilson's disease. Excessive levels of copper lead to neurological abnormalities and hepatic dysfunction.

The most commonly reported adverse reaction with trientine is nausea. Serious iron deficiency anaemia and severe colitis may occur during treatment.

Cuprior is a hybrid medicine<sup>2</sup> of Trientine dihydrochloride 300 mg capsules (equivalent to 200 mg trientine base) which have been authorised in the EU since 08 August 1985. Cuprior works in the same way as the reference product but, unlike the reference product, the trientine salt in Cuprior (tetrahydrochloride) does not require refrigerated storage.

The full indication is: "Cuprior is indicated for the treatment of Wilson's disease in adults, adolescents and children  $\geq$  5 years intolerant to D-penicillamine therapy."

It is proposed that treatment with Cuprior be initiated by physicians experienced in the treatment 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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

