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EPAR summary for the public

Cuprior

trientine

This is a summary of the European public assessment report (EPAR) for Cuprior. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Cuprior.

For practical information about using Cuprior, patients should read the package leaflet or contact their doctor or pharmacist.

What is Cuprior and what is it used for?

Cuprior is a medicine used to treat patients aged 5 years and older with Wilson's disease, a genetic condition in which copper absorbed from food builds up in the body, particularly in the liver and the brain, causing damage. Cuprior is used in patients who cannot take D-penicillamine, another medicine for this condition.

Cuprior contains the active substance trientine. It is a hybrid medicine. This means that it is similar to a 'reference medicine' (in this case Trientine Dihydrochloride 300 mg capsules) also containing trientine. The difference between Cuprior and the reference medicine is that Cuprior contains another form of trientine (trientine tetrahydrochloride) and does not need to be stored in a refrigerator.

How is Cuprior used?

Cuprior can only be obtained with a prescription and treatment should be started by a specialist with experience in the management of Wilson's disease.

Cuprior is available as 150 mg tablets. In adults, the total recommended daily dose is from 3 to 6.5 tablets, and in children from 1.5 to 4 tablets. The tablets are taken in 2 to 4 divided doses. Doses are adjusted according to patient response and levels of copper in the body. Cuprior should be taken on an empty stomach, at least one hour before or two hours after meals.

For further information, see the package leaflet.

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How does Cuprior work?

The active substance in Cuprior, trientine, is a chelating agent. It works by attaching to copper in the body and forming a complex that is then eliminated in the urine.

How has Cuprior been studied?

The company provided data from the published literature, which show that trientine significantly increases copper elimination in the urine.

The company also carried out a study to compare the levels of trientine in the blood after having taken Cuprior with those for the reference medicine. Results showed that Cuprior produces higher levels of the active substance in the blood than the reference medicine. To take account of this difference, Cuprior is used at lower doses.

What are the benefits and risks of Cuprior?

Since Cuprior is a hybrid medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Cuprior approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Cuprior's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP noted that trientine has been used for over 30 years to treat patients with Wilson's disease. Although Cuprior releases more trientine in the body than the reference medicine, this difference can be addressed by lowering the dose, which is in any case adjusted according to patient response and levels of copper in the body.

What measures are being taken to ensure the safe and effective use of Cuprior?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cuprior have been included in the summary of product characteristics and the package leaflet.

Other information about Cuprior

The European Commission granted a marketing authorisation valid throughout the European Union for Cuprior on 5 September 2017

The full EPAR for Cuprior can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Cuprior, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Cuprior can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 09-2017.