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EPAR summary for the public

Cuprymina

copper (^{64}Cu) chloride

This is a summary of the European public assessment report (EPAR) for Cuprymina. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Cuprymina.

What is Cuprymina?

Cuprymina is a solution that contains the radioactive substance copper (^{64}Cu) chloride. ^{64}Cu is a radioactive form of copper.

What is Cuprymina used for?

Cuprymina is not used on its own but is used for radiolabelling other medicines. Radiolabelling is a technique where a substance is labelled with a radioactive compound. Once the substance is radiolabelled with Cuprymina, it then carries the radioactivity to where it is needed in the body.

Cuprymina is used to radiolabel medicines that have been specially developed for use with copper (^{64}Cu) chloride.

Medicines to be radiolabeled with Cuprymina can only be obtained with a prescription.

How is Cuprymina used?

Cuprymina is only to be used by specialists who have experience in radiolabelling. Cuprymina is never given directly to the patient. Radiolabelling of a medicine takes place outside the body in a laboratory setting. The radiolabelled medicine is then given to the patient according to the instructions in that medicine's summary of product characteristics (SmPC).

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How does Cuprymina work?

The active substance in Cuprymina, copper (^{64}Cu) chloride, is a radioactive compound that emits a type of radiation known as beta radiation. When a medicine is radiolabelled with Cuprymina, the medicine will carry the radiation to the particular site or type of cell in the body that is targeted by the medicine. The intended effect of the radiation will depend on the nature of the medicine that has been radiolabelled.

How has Cuprymina been studied?

The company presented information from the scientific literature on the potential uses of Cuprymina. Some of the scientific literature presented showed how radiolabelling with radioactive forms of Copper, including ^{64}Cu, were used together with imaging techniques to detect the site and spread of tumours and how it could potentially be used to treat various types of cancer.

What benefit has Cuprymina shown during the studies?

The information supplied by the company showed that Cuprymina can be used to radiolabel medicines with ^{64}Cu, with potential utility for detecting of the sites and spread of tumours.

What is the risk associated with Cuprymina?

The side effects with Cuprymina depend largely on the medicine it has been used to radiolabel and will be described in that medicine's package leaflet. Cuprymina itself is radioactive and so its use in radiolabelling may carry a risk of cancer and hereditary defects. The doctor will ensure that the risks linked to the radioactive exposure are lower than the risks from the disease itself.

Cuprymina must not be given directly to any patient. It must not be used in people who are hypersensitive (allergic) to copper (^{64}Cu) chloride or any of the other ingredients. It must not be used in women who are known to be or may be pregnant. More information on the restrictions on the use of medicines radiolabelled with Cuprymina will be found in their package leaflets.

Why has Cuprymina been approved?

Given the well-known risks of exposure to radiation through radiolabeling, the Committee decided that Cuprymina is only to be used if justified by the likely medical benefit. The CHMP considered that there are no major safety concerns with regard to potential copper toxicity, since Cuprymina is used at very low doses. Therefore, the CHMP decided that Cuprymina's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Cuprymina

The European Commission granted a marketing authorisation valid throughout the European Union for Cuprymina on 23 August 2012.

The full EPAR for Cuprymina 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 Cuprymina, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2012.