



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Cuprymina copper (⁶⁴Cu) chloride

On 21 June 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cuprymina, 925 MBq/ml, radiopharmaceutical precursor. Cuprymina is a radiopharmaceutical precursor, not intended for direct use in patients, and is to be used only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide. The applicant for this medicinal product is SPARKLE S.r.l. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Cuprymina is copper (⁶⁴Cu) chloride, a radioactive compound that emits beta radiation. The effect of copper (⁶⁴Cu) chloride depends on the nature of the medicine that is radiolabelled with it.

Since Cuprymina is not intended for direct administration without conjugation to carrier molecules, no clinical data with the use of Cuprymina alone have been submitted. However, information demonstrating the clinical utility of the radiopharmaceutical when attached to relevant carrier molecules was presented. A potential clinical utility for Cuprymina radiolabelled molecules was shown in the molecular imaging of tumours. Another potential area of clinical utility is the detection of hypoxic areas within tumours.

Unfavourable effects relating to the radioactivity would be expected as for all radionuclides in clinical use. These include carcinogenicity, mutagenicity, and effects on different tissues. These would be dependant on the radiation characteristics of copper (⁶⁴Cu) chloride in Cuprymina as well as on the carrier molecule to which Cuprymina is labelled. In addition to radiation exposure to the patient, the risk of radiation exposure to other individuals is also a risk, considering the emission of high energy gamma rays from copper (⁶⁴Cu) chloride. Further comment on whether the risk is acceptable in any particular case can only be made in subsequent applications for carrier molecules intending to use Cuprymina as a radiolabel, for use in specific indications.

A pharmacovigilance plan for Cuprymina will be implemented as part of the marketing authorisation.

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.



The approved indication is: "Cuprymina is a radiopharmaceutical precursor. It is not intended for direct use in patients. This medicinal product must be used only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide." It is proposed that Cuprymina be prescribed by physicians experienced in *in-vitro* radiolabelling.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Cuprymina and therefore recommends the granting of the marketing authorisation.