



23 April 2015
EMA/247591/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Lumark

Lutetium (¹⁷⁷Lu) chloride

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lumark, a radiopharmaceutical precursor. Lumark is not intended for direct use in patients and must be used only for radiolabelling carrier molecules specifically developed to be used with Lumark. The applicant for this medicinal product is I.D.B. Radiopharmacy B.V.

Lumark will be available as an 8 to 400 GBq Lutetium (¹⁷⁷Lu) radiopharmaceutical precursor solution. The active substance of Lumark is ¹⁷⁷Lu, a radioactive isotope of lutetium that emits beta and gamma radiation. The effect of Lumark depends on the nature of the medicine that is radiolabelled with it.

Since Lumark is not intended for direct administration without conjugation to carrier molecules, no clinical data with the use of Lumark alone have been submitted. However, information demonstrating the clinical utility of Lumark when attached to relevant carrier molecules was presented, for example in the molecular imaging of neuroendocrine tumours.

Unfavourable effects relating to radiation exposure can occur with Lumark as is the case with all radionuclides in clinical use. These effects, which include carcinogenicity and mutagenicity, will depend on the radiation characteristics of lutetium (¹⁷⁷Lu) chloride in Lumark and on the carrier molecule to which Lumark is labelled. In addition to radiation exposure to the patient, there is also a risk of radiation exposure to other individuals in close proximity to the patient. A judgement on whether the risk is acceptable in any particular case can only be made in subsequent applications for carrier molecules intending to use Lumark as a radiolabel.

The full indication is: "Lumark is a radiopharmaceutical precursor. It is not intended for direct use in patients. This medicinal must be used only for the radiolabelling of carrier molecules, which have been specifically developed for radiolabelling with this radionuclide". It is recommended that Lumark only be used by specialists experienced with in vitro radiolabelling.

Detailed recommendations for the use of this product will be described in the summary of product

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



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.

Medicinal product no longer authorised