29 May 2019
EMA/CHMP/276812/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

LysaKare

Arginine/lysine

On 29 May 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product LysaKare, intended for protecting the kidneys against radiation during radioactive therapy with lutetium (^{177}Lu) oxodotreotide. The applicant for this medicinal product is Advanced Accelerator Applications.

LysaKare will be available as 25 g / 25 g solution for infusion. The active substances of LysaKare are the amino acids L-Arginine Hydrochloride and L-Lysine Hydrochloride (ATC code: V03AF11) that decrease reabsorption and retention of lutetium (^{177}Lu) oxodotreotide in the kidney tubules.

The benefits with LysaKare are its ability to reduce exposure of the kidneys to radiation from lutetium (^{177}Lu) oxodotreotide. The most common side effects are nausea and vomiting.

The full indication is: "Reduction of renal radiation exposure during peptide-receptor radionuclide therapy (PRRT) with lutetium (^{177}Lu) oxodotreotide in adults." It is proposed that LysaKare be administered by physicians experienced in radioactive therapy.

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.

[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

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