29 January 2026
EMADOC-1829012207-40538
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ilumira

lutetium (^{177}Lu) chloride

On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ilumira, a radiopharmaceutical precursor. Ilumira is not intended for direct use in patients and must be used only for the radiolabelling of carrier medicines that have been specifically developed and authorised for radiolabelling with lutetium (^{177}Lu) chloride.

The applicant for this medicinal product is SHINE Europe B.V.

Ilumira will be available as a solution containing 37 GBq/ml radiopharmaceutical precursor. The active substance of Ilumira is lutetium (^{177}Lu) chloride, a therapeutic radiopharmaceutical (ATC code: V10X), which is a radioactive isotope of lutetium that emits beta-minus and gamma radiation. The effect of Ilumira depends on the nature of the carrier medicine radiolabelled with the product.

The clinical utility of lutetium (^{177}Lu) when attached to relevant carrier medicines was demonstrated based on an extensive review of the literature, for example in the treatment of patients with neuroendocrine tumours or prostate cancer. Unfavourable effects relating to radiation exposure can occur with Ilumira, as is the case with all radionuclides in clinical use. These effects, which include carcinogenicity and mutagenicity, will depend on the carrier medicine radiolabelled with lutetium (^{177}Lu).

In addition to radiation exposure for the patient, there is also a risk of radiation exposure for individuals in close proximity to the patient. A judgement on whether these risks are acceptable in any particular case can only be made in subsequent applications for carrier medicines intending to use Ilumira as a radiolabel.

The full indication is:

> Ilumira is a radiopharmaceutical precursor, and it is not intended for direct use in patients. It is to be used only for the radiolabelling of carrier molecules that have been specifically developed and authorised for radiolabelling with lutetium (^{177}Lu) chloride.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Ilumira should 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 characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.