EMA/48983/2026
EMEA/H/C/006596

Ilumira (*lutetium (^{177}Lu) chloride*)

An overview of Ilumira and why it is authorised in the EU

What is Ilumira and what is it used for?

Ilumira is a solution containing a radioactive form of lutetium (^{177}Lu) that 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 Ilumira, it then carries the radioactivity to where it is needed in the body (for example, the site of a tumour) to either treat a disease or to obtain images.

Ilumira is never given directly to a patient.

Ilumira contains the active substance lutetium (^{177}Lu) chloride and is used to radiolabel medicines that have been specifically developed for use with lutetium (^{177}Lu) chloride.

How is Ilumira used?

Ilumira is only to be used by specialists who have experience in radiolabelling. Radiolabelling of a medicine takes place 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).

How does Ilumira work?

When a medicine is radiolabelled with Ilumira, the medicine will carry the radioactive part of Ilumira, lutetium (^{177}Lu), to the particular site in the body or type of cell in the body that is targeted by the medicine. Lutetium (^{177}Lu) will then emit a type of radiation known as beta-minus, which is used for treatment, as well as a small amount of radiation called gamma radiation, which is used for imaging. The amount of Ilumira used for radiolabelling depends on the medicine to be radiolabelled and its intended use.

What benefits of Ilumira have been shown in studies?

The company presented information from published clinical studies on the potential uses of Ilumira. Some of the data presented showed the usefulness of ^{177}Lu in radiolabelling medicines for treating neuroendocrine tumours and prostate cancer, used together with imaging techniques to detect the site and spread of tumours.

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What are the risks associated with Ilumira?

For the full list of side effects and restrictions with Ilumira, see the package leaflet.

The side effects depend largely on the medicine that has been radiolabelled with Ilumira. Information on the side effects and restrictions with medicines radiolabelled with Ilumira can be found in the respective package leaflets.

Ilumira itself is radioactive and so the use of medicines radiolabelled with Ilumira may carry a risk of developing 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.

The most common side effects (which may affect more than 1 in 10 people) include anaemia (low levels of red blood cells), thrombocytopenia (low levels of blood platelets), leucopenia (low levels of white blood cells), lymphopenia (low levels of lymphocytes, a particular type of white blood cell), nausea (feeling sick), vomiting and hair loss.

Ilumira must not be used in women who are known to be or may be pregnant, and when pregnancy has not been ruled out.

Why is Ilumira authorised in the EU?

The European Medicines Agency decided that Ilumira's benefits for radiolabelling medicines are greater than its risks and it can be authorised for use in the EU. As Ilumira is not intended for use on its own, its benefits and risks will also be assessed independently when added to a medicine.

What measures are being taken to ensure the safe and effective use of Ilumira?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ilumira have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ilumira are continuously monitored. Suspected side effects reported with Ilumira are carefully evaluated and any necessary action taken to protect patients.

Other information about Ilumira

Ilumira received a marketing authorisation valid throughout the EU on 26 March 2026.

Further information on Ilumira can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/ilumira

This overview was last updated in 03-2026.