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ilLuzyce (*lutetium (^{177}lu) chloride*)

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

What is ilLuzyce and what is it used for?

ilLuzyce 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 ilLuzyce, it then carries the radioactivity to where it is needed in the body (for example, the site of a tumour).

ilLuzyce is used to radiolabel medicines that have been specifically developed for use with lutetium (^{177}lu) chloride.

ilLuzyce contains the active substance lutetium (^{177}lu) chloride.

How is ilLuzyce used?

ilLuzyce is only to be used by specialists who have experience in radiolabelling. ilLuzyce is never given directly to a patient. 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 ilLuzyce work?

The active substance in ilLuzyce, lutetium (^{177}lu) chloride, is a radioactive compound that emits mainly a type of radiation known as 'beta-minus', for treatment, and a small amount of gamma radiation, for imaging. When a medicine is radiolabelled with ilLuzyce, the medicine will carry the radiation to the particular site or type of cell in the body that is targeted by the medicine.

What benefits of ilLuzyce have been shown in studies?

The company presented information from published clinical studies on the potential uses of ilLuzyce. Some of the data presented showed the usefulness of ^{177}Lu in radiolabelling medicines for treating neuroendocrine tumors 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 ilLuzyce?

The side effects with ilLuzyce depend largely on the medicine it has been used to radiolabel and will be described in that medicine's package leaflet. ilLuzyce itself is radioactive and so its use in radiolabelling 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) are anaemia (low red blood cell counts), thrombocytopenia (low blood platelet counts), leucopenia (low white blood cell counts), lymphopenia (low levels of lymphocytes, a particular type of white blood cell), nausea (feeling sick), vomiting and hair loss.

ilLuzyce must not be given directly to any patient. It must not be used in women who are known to be or may be pregnant, and when pregnancy has not been ruled out. For the full list of restrictions of ilLuzyce, see the package leaflet.

Information on the restrictions on the use of medicines radiolabelled with ilLuzyce can be found in the respective package leaflets.

Why is ilLuzyce authorised in the EU?

The European Medicines Agency decided that ilLuzyce's benefits for radiolabelling medicines are greater than its risks and it can be authorised for use in the EU. Given the well-known risks linked to radiation exposure, the Agency concluded that ilLuzyce is only to be used if justified by the likely medical benefit.

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

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

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

Other information about ilLuzyce

ilLuzyce received a marketing authorisation valid throughout the EU on 15 September 2022.

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

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