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

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

What is Lumark and what is it used for?

Lumark contains the radioactive compound lutetium (^{177}Lu) chloride and is used for radiolabelling other medicines. Radiolabelling is a technique for tagging (or labelling) medicines with radioactive compounds so they can carry radioactivity to where it is needed in the body, for example, the site of a tumour.

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

How is Lumark used?

Lumark is only used by specialists who have experience in radiolabelling.

Lumark is never given to a patient on its own. Radiolabelling with Lumark takes place in a laboratory. The radiolabelled medicine is then given to the patient according to the instructions in that medicine's product information.

How does Lumark work?

The active substance in Lumark, lutetium (^{177}Lu) chloride, is a radioactive compound that mainly releases beta radiation, with small amounts of gamma radiation. When a medicine is radiolabelled with Lumark, the medicine carries the radiation to where it is needed in the body, either to kill cancer cells (when used for treatment) or to obtain images on a screen (when used for diagnosis).

What benefits of Lumark have been shown in studies?

Because the use of lutetium (^{177}Lu) to radiolabel medicines is well established, the company presented data from the scientific literature. Several published studies have established the usefulness of lutetium (^{177}Lu) in radiolabelling medicines for diagnosing and treating neuroendocrine tumours. These tumours affect hormone-secreting cells in many parts of the body, including the pancreas, intestine, stomach and lungs.

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How well Lumark works will largely depend on the medicine that it is used to radiolabel.

What are the risks associated with Lumark?

The side effects with Lumark depend largely on the medicine it is used with and are described in that medicine's package leaflet. Lumark itself is radioactive, and as with any other radioactive product, its use may carry a risk of developing cancer and hereditary defects. However, the quantity of Lumark to be used is very small and therefore these risks are considered low. The doctor will ensure that the expected benefit to the patients of using Lumark outweigh the risks linked to the radioactivity.

The most common side effects with Lumark (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 mild and temporary hair loss.

Medicines radiolabelled with Lumark must not be used in women unless pregnancy has been ruled out. For the list of all side effects and restrictions with Lumark, see the package leaflet. Information on restrictions that apply specifically to medicines radiolabelled with Lumark can be found in the package leaflets of those medicines.

Why is Lumark authorised in the EU?

The European Medicines Agency considered that the use of lutetium (^{177}Lu) for radiolabelling medicines was well established and well documented in the scientific literature. As with all radiolabelling materials for medicines, there are risks linked to radiation exposure from Lumark. Information on how to minimise the risks is included in the product information for Lumark.

The Agency concluded that the benefits of Lumark outweigh the risks and it can be authorised for use in the EU.

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

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

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

Other information about Lumark

Lumark received a marketing authorisation valid throughout the EU on 19 June 2015.

Further information on Lumark can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.