



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EndolucinBeta (*lutetium (<sup>177</sup>Lu) chloride*)

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

### What is EndolucinBeta and what is it used for?

EndolucinBeta contains the radioactive compound lutetium (<sup>177</sup>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.

EndolucinBeta is to be used to radiolabel medicines that have been specifically developed for use with lutetium (<sup>177</sup>Lu) chloride.

### How is EndolucinBeta used?

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

EndolucinBeta is never given to a patient on its own. Radiolabelling with EndolucinBeta 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 EndolucinBeta work?

The active substance in EndolucinBeta, lutetium (<sup>177</sup>Lu) chloride, is a radioactive compound that mainly releases beta radiation, with small amounts of gamma radiation. When a medicine radiolabelled with EndolucinBeta is given to a patient, it 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 EndolucinBeta have been shown in studies?

Several published studies have established the usefulness of lutetium (<sup>177</sup>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. How well EndolucinBeta works will largely depend on the medicine that it is used to radiolabel.



## **What are the risks associated with EndolucinBeta?**

The side effects with EndolucinBeta depend largely on the medicine it is used with and are described in that medicine's package leaflet. EndolucinBeta itself is radioactive, and as with any other radioactive product, its use may carry a risk of developing cancer and defects that are passed on to children. However, the quantity of EndolucinBeta 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 EndolucinBeta outweigh the risks linked to the radioactivity.

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

## **Why is EndolucinBeta authorised in the EU?**

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

The Agency concluded that the benefits of EndolucinBeta 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 EndolucinBeta?**

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

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

## **Other information about EndolucinBeta**

EndolucinBeta received a marketing authorisation valid throughout the EU on 6 July 2016.

Further information on EndolucinBeta can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports).

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