



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Lutathera

lutetium (^{177}Lu) oxodotreotide

This is a summary of the European public assessment report (EPAR) for Lutathera. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lutathera.

For practical information about using Lutathera, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lutathera and what is it used for?

Lutathera is a cancer medicine for treating tumours in the gut known as gastroenteropancreatic neuroendocrine tumours (GEP-NETs). It is a radiopharmaceutical (a medicine that emits a small amount of radioactivity).

Lutathera is used to treat GEP-NETs that cannot be removed by surgery, have spread to other parts of the body or are not responding to treatment.

The medicine is only for GEP-NETs that have receptors called somatostatin receptors on their cell surfaces.

Because the number of patients with GEP-NETs is low, they are considered 'rare', and Lutathera was designated an 'orphan medicine' (a medicine used in rare diseases) on 31 January 2008.

Lutathera contains the active substance lutetium (^{177}Lu) oxodotreotide.

How is Lutathera used?

Because Lutathera emits some radioactivity, it is only used in special controlled areas and must be handled and given to patients by qualified personnel. The patient cannot leave the controlled areas until told to do so by the doctor.



Before starting treatment, the doctor will have checked that the patient's tumours have somatostatin receptors on their cell surfaces. Lutathera is given by infusion (drip) into a vein. The usual treatment involves 4 infusions 8 weeks apart, but the gap between infusions can be increased to up to 16 weeks if the patient gets severe side effects. The patient should also be given an infusion of an amino acid solution which helps protect their kidneys.

For further information, including information on the precise method for giving the infusions, see the package leaflet.

How does Lutathera work?

The active substance in Lutathera, lutetium (¹⁷⁷Lu) oxodotreotide, works by attaching to somatostatin receptors, which are found in high numbers in some GEP-NETs. The radioactivity it emits then kills the tumour cells it is attached to but has little effect on neighbouring cells.

What benefits of Lutathera have been shown in studies?

Lutathera can help slow down the worsening of GEP-NETs. In a main study of 229 patients with GEP-NETs that contained somatostatin receptors, patients given Lutathera lived for an average of 28 months without their disease getting worse. This compares with around 9 months for patients treated with octreotide, a medicine already approved for treating the condition.

What are the risks associated with Lutathera?

The most common side effects seen with Lutathera treatment are nausea and vomiting, which occurred at the start of the infusions in around half of patients and may be related to the amino acid infusion. Other common side effects affecting more than 1 in 10 patients are thrombocytopenia (low platelet counts), lymphopenia (low levels of lymphocytes, a type of white blood cell), anaemia (low red cell counts), pancytopenia (low levels of all types of blood cells), tiredness and reduced appetite. For the full list of all side effects reported with Lutathera, see the package leaflet.

Lutathera must not be given to women who are pregnant or in whom pregnancy has not been excluded. It must also not be given to patients with severely reduced kidney function. For the full list of restrictions, see the package leaflet.

Why is Lutathera approved?

Only a minority of patients with GEP-NETs can be cured with surgery and at the time of diagnosis the tumours would have spread in most patients. Lutathera can help slow the worsening of the condition and its side effects are considered manageable.

The European Medicines Agency considered that the benefits seen with Lutathera outweigh its risks and recommended it be approved in the EU.

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

The company that markets Lutathera will put in place an educational programme for patients to ensure they understand the risk of radioactivity and precautions they should take to limit exposure to themselves and people around them.

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

Other information about Lutathera

The European Commission granted a marketing authorisation valid throughout the European Union for Lutathera on 26 September 2017.

The full EPAR for Lutathera can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports. For more information about treatment with Lutathera, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Lutathera can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/Rare_disease_designation.

This summary was last updated in 09-2017.