Advanced Accelerator Applications

A Novartis Company

LUTATHERA®

Lutetium (^{177}Lu) oxodotreotide

A guide for patients

This leaflet has been created and funded by
Advanced Accelerator Applications, A Novartis Company.

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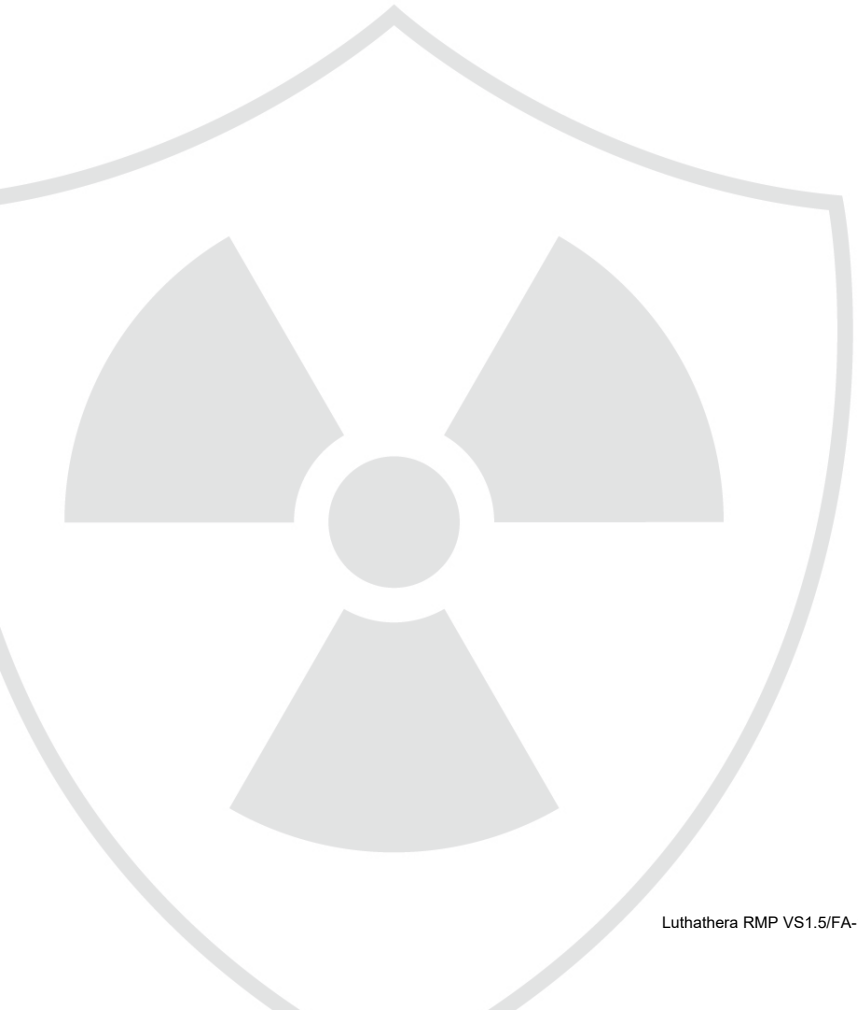


WHAT IS IN THIS LEAFLET

This leaflet has been created to provide you with information about LUTATHERA®.

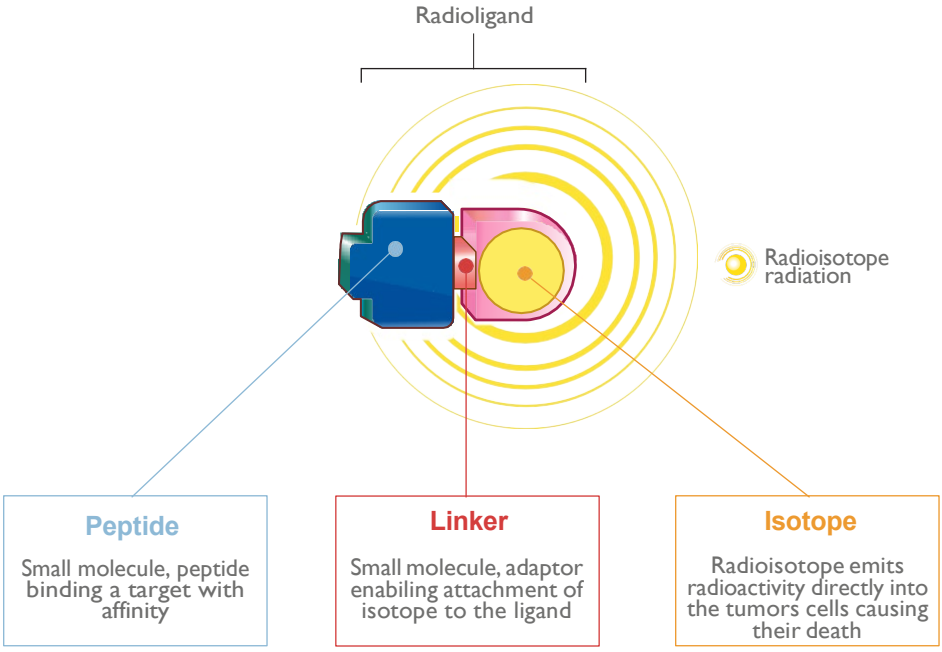
If you have any further questions, please ask a member of the nuclear medicine team who are supervising your therapy. If you get any side effects, including side effects not listed in this leaflet, please talk to your nuclear medicine physician.

WHAT LUTATHERA® IS AND WHAT IT IS USED FOR

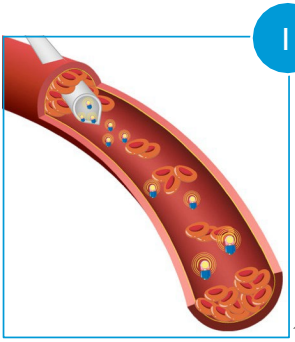
LUTATHERA® is a radiopharmaceutical therapy used for the treatment of certain tumours (gastroenteropancreatic neuroendocrine tumours), which cannot be completely removed from your body by surgery, have spread in your body (metastatic) and are not responding anymore to your current treatment. The tumour needs to have somatostatin receptors on the surface of its cells in order for the medicine to be effective. LUTATHERA® binds with these receptors and delivers radioactivity directly into the tumour cells, causing their death.

The active substance of LUTATHERA® is made of three components:

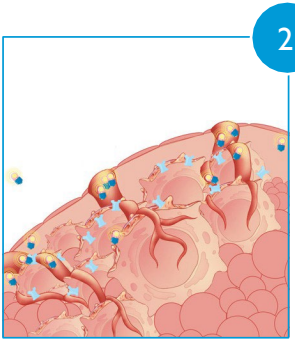
- A peptide, which targets the somatostatin receptors on the surface of the tumour cells
- A radioactive element: the radionuclide that emits radiation
- A linker which connects the above two elements



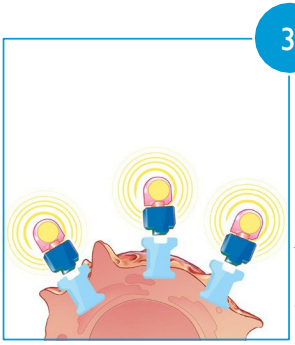
HOW LUTATHERA® WORKS



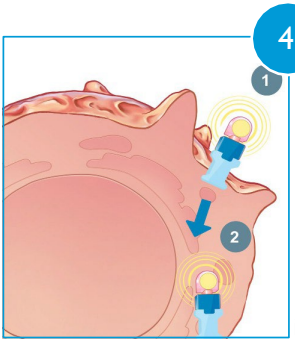
Infusion into the bloodstream



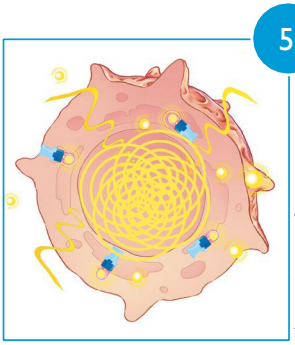
Somatostatin receptors concentration into NET sites



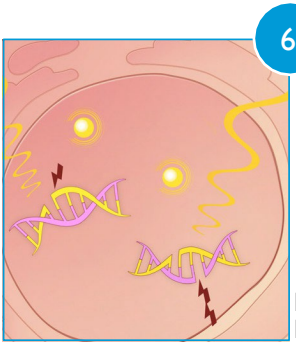
LUTATHERA® binds to somatostatin receptors overexpressed by NET cells



LUTATHERA® is internalised into NET cells



The radiopeptide delivers radiation within the NET cells



Radiation causes NET cell death

Following infusion into the bloodstream, LUTATHERA® rapidly accumulates within tumour cells. Here, it delivers its radiation, thereby causing tumour cell death.

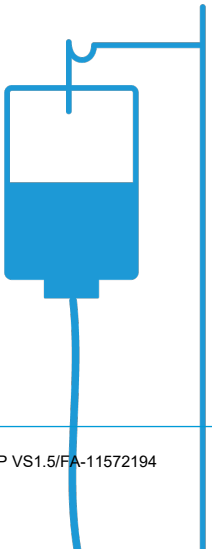
WHAT YOU NEED TO KNOW BEFORE LUTATHERA® IS ADMINISTERED

- On the recommendation of your healthcare team, you have agreed to receive LUTATHERA® treatment
- The use of LUTATHERA® involves exposure to radioactivity. As for all treatments, your doctor has decided that the clinical benefit that you will obtain from LUTATHERA® outweighs the treatment risks
- Radiopharmaceuticals require certain precautions in order to limit unnecessary exposure to yourself and the people around you

What do I need to tell my doctor?

Be sure to tell your healthcare team everything about your disease, including:

- Symptoms
- Allergies
- All medicines you are taking (in particular, if you are taking somatostatin analogues, you might be asked to stop and/or adapt your treatment for a short period of time)
- Foods you eat
- Any change in your daily habits



HOW LUTATHERA® IS ADMINISTERED

LUTATHERA® will be administered to you in a hospital, in a controlled area specialised in nuclear medicine. Nuclear medicine healthcare professionals are trained and qualified to use radiopharmaceuticals safely. They will take special care to ensure the safe use of LUTATHERA® and will keep you informed of their actions.

Duration of the procedure

Your nuclear medicine team will inform you about the usual duration of the procedure. LUTATHERA® is administered at the hospital by infusion (via a drip) into a vein. The radiopharmaceutical infusion takes 20 to 40 minutes, however, the complete administration procedure will take approximately 5 hours.

Other products administered during the procedure

LUTATHERA® is almost exclusively eliminated through the renal system (kidneys). For kidney protection, an infusion of amino acids will also be given to you before, during and after your LUTATHERA® infusion. This amino acids infusion will take about 4 hours.

The administration of amino acids may induce nausea and vomiting. To manage these symptoms, an antiemetic drug (to prevent nausea and vomiting) will be injected to you before the start of the amino acids infusion.

After administration, the radiopharmaceuticals which do not bind to the tumour are rapidly eliminated from your body, mostly through excretion in urines. The doctor will authorise you to leave the controlled area or the hospital as soon as the radiation exposure to people around you does not exceed regulatory limits.

SPECIFIC PRECAUTIONS

Considering current knowledge in this field and the physical and pharmaceutical properties of LUTATHERA®, it is estimated that the health risks to your family members and the general public are low.[1] Use of radiopharmaceuticals requires necessary precautions to reduce the radiation dose to people you may come into contact with.

At the hospital

- During the administration procedure, you will probably be isolated from other patients
- Before, during and after the infusion of LUTATHERA®, you should drink plenty of water in order to urinate as often as possible, to facilitate the elimination of the radiopharmaceutical from your body

At home

- In general, you should limit close contact with people who live with you by keeping a distance of at least one metre for 7 days after LUTATHERA® administration
- Limit close contact (less than one metre distance) with children and/or pregnant women to less than 15 minutes per day for 7 days after LUTATHERA® administration
- Sleep in separate bedrooms from other people for 7 days after LUTATHERA® administration
- Sleep in separate bedrooms from children and/or pregnant women for 15 days after LUTATHERA® administration

Restrictions to follow after each administration of LUTATHERA®	Amount of days
Daytime restrictions	
Avoid close contact (less than 1 metre distance) with people who live with you	7
Limit close contact (less than 1 metre) with children and pregnant women to less than 15 minutes per day	7
Nighttime restrictions	
Sleep in a separate bedroom from other people	7
Sleep in a separate bedroom from children and/or pregnant women	15

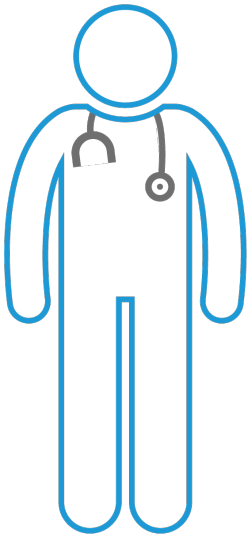
For the first 7 days after administration

- On the day of infusion and the day after: drink a sufficient amount of water to urinate frequently in order to eliminate the medicine from your body
- Try to defaecate every day (use laxatives if needed)
- Use toilets in a seated position, even for men and use toilet paper each time. Flush wipes and/or toilet paper down the toilet (flush twice). It is also important to wash your hands carefully to avoid contaminating the door handles
- Take a shower every day
- Flush any tissues or any other items that contain anything from your body, such as blood, urine and faeces down the toilet. Items that cannot be flushed down the toilet, such as feminine hygiene products and bandages, must be placed in separate rubbish bags, not with other household rubbish (a member of hospital staff will tell you how to discard the bags)
- Wash your undergarments, pyjamas, sheets and any clothes that contain sweat, blood or urine separately from the laundry of other members of your household. Use a standard washing machine; you do not need to use bleach and do not need extra rinses.
- People who are confined to the bed or have reduced mobility will preferably receive assistance by a care provider. It is recommended that when providing assistance in the bathroom, the care provider wears disposable gloves for 7 days after administration. In the case of the use of special medical equipment such as catheters, colostomy bags, bedpan, water nozzle, or anything that could be contaminated by your body fluids these must be emptied immediately into the toilet and then cleaned
- If anyone helps you clean up vomit, blood, urine, or stool they should wear plastic gloves; the gloves should then be disposed of in a separate rubbish bag as described above

POSSIBLE SIDE EFFECTS

Like all medicines, LUTATHERA® can cause side effects, although not everybody gets them. The list of possible side effects is provided in the patient information leaflet attached to this brochure.

For more information, please speak to your doctor.



Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000.

E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of **Lutathera** to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.novartis.com/report or by e-mail at drug_safety.malta@novartis.com.

Marketing Authorization Holder: Advanced Accelerator Application 8-10 Rue Henri Sainte-Claire Deville 92500 Rueil-Malmaison France "

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For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm **- and download the required material with the latest date.**

This educational material is a part of the conditions of the Marketing Authorisation"

For more detailed guidance on **Lutathera** please refer to the Summary of Product Characteristics (SmPC) available at https://www.ema.europa.eu/en/documents/product-information/lutathera-epar-product-information_en.pdf

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