LUTATHERA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using LUTATHERA?

LUTATHERA contains the active ingredient lutetium (177Lu) oxodotreotide. LUTATHERA is used for the treatment of adults with certain tumours (gastroenteropancreatic neuroendocrine tumours). For more information, see Section 1. Why am I using LUTATHERA? in the full CMI.

2. What should I know before I use LUTATHERA?

Do not use if you have ever had an allergic reaction to lutetium (177Lu) oxodotreotide, amino acid solutions or any of the ingredients listed at the end of the CMI, you are pregnant or think you may be pregnant, if your kidneys are seriously impaired, or if you have

any problem with the breakdown of amino acids in your body. The radiation coming from the medicine may potentially decrease your fertility. **Talk to your doctor if you have any concerns, including whether you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**
For more information, see Section 2. What should I know before I use LUTATHERA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LUTATHERA and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use LUTATHERA?

- LUTATHERA is given in a hospital or other licensed facility by specially trained staff.
- LUTATHERA is given as a single infusion into your vein approximately every 8 weeks for a total of 4 times.

More instructions can be found in Section 4. How do I use LUTATHERA? in the full CMI.

5. What should I know while using LUTATHERA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LUTATHERA. • Drink plenty of water e.g. 1 glass of water every hour on the day of infusion and the day after. • Limit close contact (less than 1 metre) with others in your household for 7 days after receiving each dose of LUTATHERA, and with children and pregnant women to less than 15 minutes per day for 7 days after receiving each dose of LUTATHERA. • Sleep in a separate bedroom from others in your household for 7 days, from children or pregnant women for 15 days after

	receiving each dose of LUTATHERA.
Things you should not do	• Do not stop using effective birth control during LUTATHERA treatment and for 7 months after completing the treatment for females and for 4 months after completing the treatment for males.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how LUTATHERA affects you.
Looking after your medicine	• You will not need to store, handle, or dispose of this medicine. • The specialist needs to store LUTATHERA below 25°C (do not freeze) and to store LUTATHERA in the original package to protect from ionising radiation (lead shielding).

For more information, see Section 5. What should I know while using LUTATHERA? in the full CMI.

6. Are there any side effects?

Very common side effects include: feeling sick, vomiting, tiredness, tummy pain, diarrhoea. More serious very common side effects include: bleeding or bruising more easily than normal or difficulty to stop bleeding, infections with signs such as fever, sore throat or mouth ulcers, tiredness, weakness, pale skin, shortness of breath, passing less urine or smaller amounts than usual.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

LUTATHERA®

Active ingredient(s): Lutetium (177Lu) oxodotreotide

Consumer Medicine Information (CMI)

This leaflet provides important information about using LUTATHERA. **You should also speak to your doctor, pharmacist or healthcare professional if you would like further information or if you have any concerns or questions about using LUTATHERA.**

Where to find information in this leaflet:

1. Why am I using LUTATHERA?
2. What should I know before I use LUTATHERA?
3. What if I am taking other medicines?
4. How do I use LUTATHERA?
5. What should I know while using LUTATHERA?
6. Are there any side effects?
7. Product details

1. Why am I using LUTATHERA?

LUTATHERA contains the active ingredient lutetium (177Lu) oxodotreotide. LUTATHERA is a radiopharmaceutical product for therapy only.

LUTATHERA is used for the treatment of adults with certain tumors called gastroenteropancreatic neuroendocrine tumors. The tumour needs to have somatostatin proteins (receptors) on the surface of its cells in order for the medicine to work. LUTATHERA binds with these receptors and sends out radioactivity directly into the tumour cells, causing them to die.

The use of LUTATHERA involves exposure to amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

2. What should I know before I use LUTATHERA?

Warnings

Do not use LUTATHERA if:

- You are allergic to lutetium (177Lu) oxodotreotide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- You are pregnant or think you may be pregnant, or it has not been confirmed you are not pregnant. You need to make sure you are not pregnant by doing a pregnancy test before starting LUTATHERA.
- Your kidneys are seriously impaired.
- You are allergic to amino acid solutions or if you have any problem with the breakdown of amino acids in your body.

Check with your doctor if you:

- have or have had kidney problems
- have or have had liver problems
- have or have had any other type of cancer or previous anti-cancer treatment (chemotherapy) or radiation therapy
- have low levels of certain types of cells in the blood (red blood cells, white blood cells, neutrophils, and platelets)
- have high levels of potassium in your blood (symptoms can include breathlessness, weakness, numbness, chest pain, tremors or abnormal heart rhythm)
- have or have had heart failure
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

You must tell your doctor and/or the nuclear medicine doctor before taking LUTATHERA if there is a possibility you might be pregnant or if you have missed your period or if you are breast-feeding.

Do not take LUTATHERA if you are pregnant as ionising radiation is dangerous for the unborn baby. Stop breast-feeding during treatment with this medicine. If treatment with LUTATHERA during breastfeeding is necessary, the child must be weaned.

Contraception

For female patients, use effective birth control during LUTATHERA treatment and for 7 months after completing the treatment.

For male patients, use effective birth control during treatment and for 4 months after completing the treatment.

Ask your doctor, pharmacist or healthcare professional for options of effective birth control.

If you are a woman who could become pregnant, your doctor or other healthcare professional will check if you are pregnant and perform a pregnancy test, if necessary, before starting treatment with LUTATHERA.

If you become pregnant or think you are pregnant after starting treatment with LUTATHERA, tell your doctor and/or nuclear medicine doctor right away.

Fertility

The radiation coming from the medicine may potentially decrease your fertility. A consultation with a genetic counsellor is recommended if you wish to have children after treatment. Preservation of sperm or eggs may be offered to you before the treatment.

Children and Adolescents

LUTATHERA has not been studied in children and adolescents under 18 years of age.

You must limit extended close contact (less than one metre) with children to less than 15 minutes per day for 7 days after receiving each dose of LUTATHERA to minimise radiation risk.

Treatment monitoring

Your specialist or healthcare professional will do blood tests before and during treatment to check your condition and to notice any side effects as early as possible. Based on the results, your specialist may decide to delay, modify, or stop your treatment with LUTATHERA if necessary.

If necessary, the electrical activity of your heart will also be checked before you are discharged from the hospital (with a test called an electrocardiogram or ECG).

3. What if I am taking other medicines?

Tell your doctor, pharmacist or healthcare professional if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with LUTATHERA and affect how it works. These include:

- somatostatin analog medicines that belong to a group of medicines called "anti-growth hormones" (somatostatin analogs) e.g. Sandostatin
- glucocorticoids (also called corticosteroids).

Check with your doctor, pharmacist or healthcare professional if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LUTATHERA.

4. How do I use LUTATHERA?

How much will I receive

- The standard dose is 7400 MBq (megabecquerel, the unit used to express radioactivity) given directly into a vein.

When will I receive LUTATHERA

- LUTATHERA is given as a single infusion once approximately every 8 weeks for a total of 4 times.

Duration of treatment

- Your nuclear medicine doctor or other healthcare professional will tell you about the usual time required for the treatment.
- The infusion of LUTATHERA takes 30 ± 10 minutes, but the complete time required will be approximately 5 hours. Your doctor will regularly monitor how you are going during this time.

During treatment with Lutathera

- During the procedure, you should isolate from other patients who are not receiving the same treatment due to the radiation released by this medicine.
- You will also be given an infusion with amino acids to protect your kidneys. This might make you feel sick and vomit and you will also receive an injection with a medicine before treatment to help decrease the sick feeling and vomiting.
- The doctor or other healthcare professional will inform you when you can leave the controlled area of the hospital.

If you miss an appointment to receive LUTATHERA

Contact your specialist or healthcare professional as soon as possible. You should receive LUTATHERA once every 8 weeks for a total of 4 times.

If you receive too much LUTATHERA

LUTATHERA is given in a hospital or other licensed facility. It is unlikely that you will receive too much. Your specialist will check and treat you if you receive too much.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LUTATHERA?

Things you should do

- drink plenty of water e.g. 1 glass of water every hour so that you urinate as often as possible on the day of infusion and the day after, and try to empty your bowels every day, in order to remove the medicine from your body.
- limit close contact (less than 1 metre) with others in your household for 7 days after receiving each dose of LUTATHERA

- limit close contact (less than 1 metre) with children and pregnant women to less than 15 minutes per day for 7 days after receiving each dose of LUTATHERA
- sleep in a separate bedroom from others in your household for 7 days, from children or pregnant women for 15 days after receiving each dose of LUTATHERA.

Use of toilets

- Take special care to avoid contamination for 7 days
- after receiving treatment:
- You must always sit when using the toilet.
- It is important that you use toilet paper every time you use the toilet.
- Always wash your hands well after using the toilet.
- Flush all wipes and/or toilet paper down the toilet immediately after use.
- Flush any tissues or any other items that contain bodily waste, such as blood, urine, and faeces (poo) down the toilet. Items that cannot be flushed down the toilet, such as sanitary pads and bandages, must be placed in separate plastic waste disposal bags (according to "Household waste disposal" below).

Showering and laundry

- Take a shower every day for at least 7 days after treatment.
- Wash your underwear, pyjamas, sheets and any clothes that contain sweat, blood or urine separately from the laundry of other members of your household,

using a standard washing cycle for 7 days after treatment. You do not need to use bleach and you do not need extra rinses.

For care givers

For 7 days after treatment:

- People who are confined to bed or have reduced mobility will preferably receive assistance from a care giver. The care giver must wear disposable gloves.
- Any special medical equipment that could be contaminated by your bodily fluids (e.g. catheters, colostomy bags, bedpans, water nozzles) must be emptied immediately into the toilet and then cleaned.
- Care givers who clean up vomit, blood, urine, or faeces (poo) should wear plastic gloves, which should be disposed of in a separate plastic waste disposal bag.

Household waste disposal

- Throw away all items in a separate plastic waste disposal bag that is to be used only for this purpose.
- Keep the plastic waste disposal bags separate from the other household waste and away from children and animals.
- A member of the hospital staff will tell you how and when to get rid of these waste disposal bags.

Hospitalisation and emergency care

- If for any reason you require emergency medical assistance or are unexpectedly admitted to the hospital during the 3 months after your treatment, please inform the healthcare professionals about the name, date, and dose of your radioactive treatment.
- Carry your discharge letter with you at all times to make it easier for 3 months after your treatment.
- Your specialist will inform you if you need to take any other special precautions after receiving this medicine. Contact your nuclear medicine doctor (your specialist) if you have any questions or are planning any travel.

Call your doctor straight away if you experience any of the following after the start of LUTATHERA treatment:

- flushing, diarrhoea, difficulty breathing with wheezing or coughing, dizziness, light-headedness (signs and symptoms of neuroendocrine hormone crisis), which may appear within the first 24 hours after LUTATHERA treatment.
- facial/throat swelling and/or difficulty breathing (signs and symptoms of angioedema).
- tiredness, loss of appetite, changes in your heartbeat, trouble thinking clearly (signs and symptoms of metabolic acidosis).

Remind any doctor, dentist, pharmacist or healthcare professional you visit that you are using LUTATHERA.

Things you should not do

- Do not stop using effective birth control during LUTATHERA treatment and for 7 months after completing the treatment for females and for 4 months after completing the treatment for males.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LUTATHERA affects you.

LUTATHERA may cause dizziness and tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- You will not have to store this medicine. This medicine is stored under the responsibility of the specialist where you were treated. Storage of radiopharmaceuticals will be in accordance with Australian regulations on radioactive materials.
- The storage instructions are for the specialist. They are: Store below 25°C. Do not freeze LUTATHERA. Store in the original package to protect from ionising radiation (lead shielding).

Getting rid of any unwanted medicine

LUTATHERA is only given in special facilities by appropriately qualified staff. They will be required to dispose of the medicine following treatment in accordance with Australian laws.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, pharmacist or healthcare professional if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Tummy problems: • Stomach pain • Constipation/diarrhoea • Vomiting • Decreased appetite • Feeling sick • Swelling, feeling of fullness in the tummy area	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, or specialist**

Less serious side effects	What to do
• Indigestion **General well-being:** • Tiredness • Dizziness • Headache • Hair loss • Muscle spasm • Muscle pain • Joint pain • Dry skin • Rash	

Serious side effects

Serious side effects	What to do
Blood problems: • Bleeding or bruising more than normal • Infections that include fever, sore throat, mouth ulcers or chills • Feeling tired or weak • Pale skin, shortness of breath • Bone marrow cancer resulting in poorly	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
formed blood cells or blood cells that do not work properly **Kidney problems:** • Passing urine less often than usual or passing much smaller amounts of urine than usual, swollen legs or feet, tiredness, shortness of breath, feeling sick	

Tell your doctor, pharmacist or healthcare professional if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What LUTATHERA contains

Active ingredient **(main ingredient)**	lutetium (177Lu) oxodotreotide
Other ingredients **(inactive ingredients)**	Acetic acid Sodium acetate Gentisic acid Ascorbic acid Pentetic acid Sodium chloride Sodium hydroxide Water for injections

Do not use this medicine if you are allergic to any of these ingredients.

What LUTATHERA looks like

LUTATHERA is supplied in a clear, colourless type I glass vial, closed with a bromobutyl rubber stopper and aluminium cap.

Each vial contains a volume that ranges from 20.5 to 25.0 mL of solution, corresponding to a radioactivity of 7400 MBq ± 10% at the date and time of infusion.

The vial is enclosed within a lead shielded container and placed in a plastic sealed container.

(Aust R 455452).

Who distributes LUTATHERA

LUTATHERA is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone: 1 800 671 203

Website: www.novartis.com.au

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