LUTATHERA®
(lutetium ^{177}Lu oxodotreotide)
Sterile Solution for intravenous infusion

Your guide to LUTATHERA® treatment

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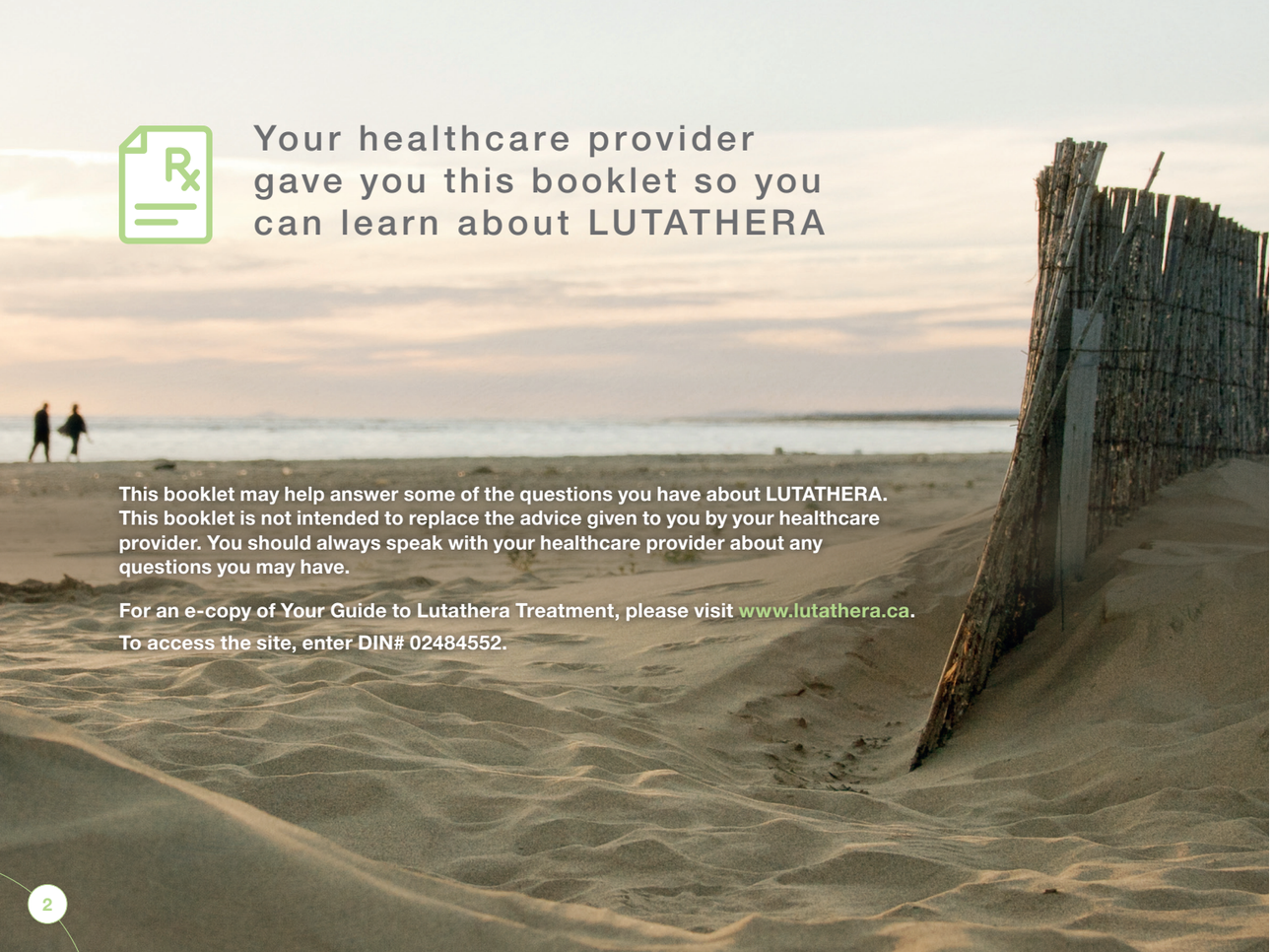

Your healthcare provider gave you this booklet so you can learn about LUTATHERA

This booklet may help answer some of the questions you have about LUTATHERA. This booklet is not intended to replace the advice given to you by your healthcare provider. You should always speak with your healthcare provider about any questions you may have.

For an e-copy of Your Guide to Lutathera Treatment, please visit www.lutathera.ca.

To access the site, enter DIN# 02484552.

What is LUTATHERA?

LUTATHERA is a radiopharmaceutical used for the treatment of certain gastroenteropancreatic neuroendocrine tumours (GEP-NETs) with somatostatin receptors, which cannot be completely removed from your body by surgery, have spread in your body and are no longer responding to your current treatment.

LUTATHERA is given as an infusion in a hospital setting.[1]

How does LUTATHERA work?

The tumour needs to have certain proteins (somatostatin receptors) on the surface of its cells in order for the medicine to work. LUTATHERA binds to these receptors, delivering radioactivity directly to the tumour cells, causing their death.

The use of LUTATHERA involves exposure to radioactivity. Your doctors have considered that the clinical benefit outweighs the risk of toxicity due to radiation.

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How is LUTATHERA given?[1]

Before you start your LUTATHERA treatment, it's important to tell your healthcare provider everything about your disease and health status. This should include:

- ✓ Symptoms you may have
- ✓ Any changes in your daily habits
- ✓ If you are pregnant, breastfeeding, or planning to become pregnant
- ✓ All the medicines you are taking

It is especially important to tell your healthcare provider if you are taking a type of medicine called a somatostatin analog. If you are taking one, you might have to stop or change your treatment for a short time before and while taking LUTATHERA.

Before your first infusion

Before your first LUTATHERA infusion, your healthcare provider may conduct a few tests to make sure you are ready for treatment. They will check your liver, kidneys, and blood. Depending on the results, they may hold off on administering LUTATHERA until you are ready.[1]

The day of therapy[1]

You will go to your healthcare provider's hospital to have LUTATHERA administered. This is done in a controlled area of the hospital. The doctors and nurses who work in this area are specially trained to use medicines like LUTATHERA.

The infusion[1]

The infusion process lasts about 5 hours.

Approximately 1 hour before you are given LUTATHERA:
You will be given a medicine that will help with any nausea that you may experience because of the treatment.

30 minutes before you are given LUTATHERA:
You will be given an amino acids infusion through an IV line. This will help protect your kidneys.

This infusion will take at least 4 hours. It will continue during and after you receive LUTATHERA.

The LUTATHERA infusion:
Will take 20 to 30 minutes and is given through IV line.

After the infusion[1]

Because LUTATHERA treatment uses radiation, a healthcare provider will inform you when you can leave the controlled area or hospital.

Your next infusion[1]

You may receive LUTATHERA 3 more times after your first infusion, for a total of 4 doses. These doses will be 8 weeks apart.

Between each dose, your healthcare provider will perform laboratory assessments of your liver, kidneys, and blood again.

After your last dose[1]

Your healthcare provider will perform laboratory assessments of your liver, kidneys, and blood on a routine basis after your last LUTATHERA dose.

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After receiving LUTATHERA[1]

Since LUTATHERA is a nuclear medicine therapy, there are some things you should do to help minimize exposure to family members and the general public.

At the hospital:

- While you are taking LUTATHERA, you will be kept away from other patients in the hospital to limit their exposure

After leaving the hospital:

General rule:

- You must avoid close contact with people who live with you and should try to keep a distance of at least one meter for 7 days after you receive LUTATHERA. When together for a prolonged period, a distance of 2 meters or more should be maintained

Contact with children and pregnant women:

- You should limit close contact with children and pregnant women for 7 days after you are given LUTATHERA. Your healthcare provider may provide further instructions to help minimize radiation exposure to others. You should always follow your healthcare provider's instructions

LUTATHERA Release Card:

Your healthcare provider may fill out a LUTATHERA release card and hand it to you after treatment. This card will list your name,the amount of medicine that you received, and a contact name and phone number. You should keep this card with you during your treatment, and for 3 months after, especially if you are traveling through an airport.

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Helpful hints and information[1]

Care providers:

- If a care provider helps you in the bathroom, they should wear disposable gloves for 7 days after you are given LUTATHERA

Showering:

- Daily showering is recommended for 7 days after receiving LUTATHERA

Breastfeeding:

- You should not breastfeed during LUTATHERA treatment

Using the toilet:

- Drink a sufficient amount of water (1 glass every hour) necessary to urinate every hour on the day of infusion and the day after. Try to defecate every day; use a laxative if necessary. These steps are needed to help remove the medicine from your body
- For a few days after you receive LUTATHERA, use the toilet in a seated position, even for men, and use toilet paper each time
- For a few days after you receive LUTATHERA, flush toilet paper and/or wipes down the toilet
- Wash your hands every time you use the toilet

Contraception:

- You should use effective contraception (for example, the pill or a condom) during LUTATHERA treatment and for 7 months after your final dose if you are a woman and for 4 months if you are a man

Side effects:

- Treatment with LUTATHERA may cause side effects. If you think you are having a side effect, you should tell your healthcare provider right away. Your healthcare provider may decide to change, pause, or stop your treatment

Possible side effects of LUTATHERA treatment

Serious Warnings and Precautions[1]

LUTATHERA should be used by health professionals who are appropriately trained and/or licensed in use of radiopharmaceuticals.

Kidney impairment can occur in patients treated with LUTATHERA. Tell your physician about any kidney condition prior to receiving LUTATHERA.

Secondary blood cancer (myelodysplastic syndrome or acute leukemia) can rarely occur several years after you have completed LUTATHERA treatment.

What are the possible side effects of LUTATHERA treatment?[1]

Like all medicines, this medicine can cause side effects, although not everybody gets them. LUTATHERA side effects are mainly linked to radioactivity and the amino acid co-infusion.

Very common side effects (may affect more than 1 in 10 people):

- Nausea (usually during the first 24 hours)
- Vomiting (usually during the first 24 hours)
- Abdominal pain
- Diarrhoea
- Fatigue (possibly delayed for more than 24 hours after treatment)
- Decreased appetite
- Pain (including back pain, arms, legs, joints, chest, bone, side or neck)
- Headache
- Dizziness (vertigo)
- Fluid retention (peripheral edema)
- Abdominal bloating (abdominal distension)
- Flushing
- Anxiety
- Increase in blood pressure (hypertension)
- Hair loss (alopecia)
- Decrease in red blood cells (anemia)
- Decrease in blood lymphocytes (lymphopenia)
- Decrease in blood platelets (thrombocytopenia)
- Decrease in blood neutrophils (neutropenia)
- Decrease in white blood cells (leukopenia)
- Change in kidney function (decreased urine output, increased blood creatinine, increased potassium in blood, increase in blood urea or uric acid, change in urine colour due to protein or blood in urine, renal failure)
- Cough
- Trouble breathing (dyspnoea)
- Increased blood sugar (hyperglycaemia)
- Decreased blood calcium (hypocalcaemia)
- Increased blood sodium (hypernatraemia)
- Decrease in blood sugar (hypoglycaemia)
- Increased blood potassium (hyperkalaemia)
- Decreased blood potassium (hypokalaemia)
- Increase in liver enzymes (alkaline phosphatase, gamma-glutamyl-transferase, aspartate aminotransferase, alanine aminotransferase)
- Increase in blood bilirubin

Common side effects (may affect up to 1 in 10 people):

- Constipation
- Indigestion (dyspepsia)
- Gas (flatulence)
- Fluid accumulation in the abdominal region (ascites) or around the lungs (pleural effusion)
- Pain in the upper abdomen
- Abdominal discomfort
- Inflammation of the stomach lining (gastritis)
- Sore mouth (stomatitis)
- Difficulty swallowing (dysphagia)
- Anal bleeding (rectal haemorrhage)
- Weakness (asthenia)
- Fever (pyrexia)
- Influenza-like illness
- Injection site pain
- Muscle spasms
- Injection site reaction
- Chills
- Chest discomfort
- Swelling
- Weight loss
- Change in heart function (increase or decrease in heart rate, inability to pump enough blood)
- Increased blood lymphocyte count (lymphocytosis)
- Decreased blood sodium (hyponatraemia)
- Dehydration
- Sleepiness (somnolence)
- Shaking (tremor)
- Decrease in blood magnesium (hypomagnesaemia)
- Vitamin D deficiency
- Disturbed sense of taste (dysgeusia)
- Fainting/loss of consciousness (syncope)
- Lack of energy (lethargy)
- Disturbed sense of smell (parosmia)
- Tingling sensation (paraesthesia)
- Low blood pressure (hypotension)
- Hot flush
- Dry mouth
- Trouble sleeping (insomnia)
- Urinary incontinence
- Rash
- Skin itching (pruritus) and redness (erythema)
- Dry skin
- Chest pain (angina pectoris)
- Bruising (contusion)
- Reduced bile flow (cholestasis)
- Decreased thyroid function (hypothyroidism, secondary hypothyroidism)
- Diabetes mellitus
- Allergic reaction (hypersensitivity)
- Infections (includes pneumonia, herpes zoster, respiratory tract infection, influenza, urinary tract infection, nasopharyngitis, bronchitis, *Clostridium difficile* infection)
- Intestinal obstruction (including small intestine)
- Blood cancers (myelodysplastic syndrome, acute leukemia)
- General decline in physical health
- Inflammation of small bulging pouches of the large intestine (diverticulitis)
- Wheezing or high-pitched whistling sound
- Change in voice (dysphonia)
- Depression
- Agitation
- Kidney stones
- Falls
- Sprains, fractures
- Tumour progression (malignancy)
- Double vision (diplopia)
- Ringing in the ears (tinnitus)
- Breast growth in men (gynecomastia)
- Inflammation of the gallbladder (cholecystitis)
- Increased blood calcium (hypercalcemia)
- Cardiac failure (including myocardial infarction)
- Gallstones
- General feeling of discomfort, illness, abnormality or uneasiness (malaise)
- Death

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Possible side effects of LUTATHERA treatment continued

LUTATHERA contributes to your overall long-term cumulative radiation exposure (the amounts of radiation that an individual typically receives from different sources over a longer period of time). Long-term cumulative radiation exposure may increase your risk for developing new cancers and increase the chances for your future children to have hereditary (from a parent) abnormalities. LUTATHERA has been associated with an increased risk for blood cancers.

If you experience any of the following side effects please speak to your healthcare professional:

- Anaemia (marked by weakness, paleness, shortness of breath, headaches, dizziness, heart palpitations)
- Thrombocytopenia, lymphopenia, neutropenia, leukopenia (marked by unusual bruising, more bleeding than usual after injury, fever, catching infections more frequently)
- Kidney injury (marked by changes in urine output and blood biochemistry)
- Liver changes (marked by changes in liver protein levels in the blood)
- Chronic blood syndromes (myelodysplastic syndrome and acute leukaemia) (marked by feeling tired, dizzy, weak, shortness of breath, pale skin, infections and abnormal bleeding)
- Neuroendocrine Hormonal Crisis (marked by flushing, diarrhoea, hypotension, difficulty breathing, usually within 24 hours of LUTATHERA dose)

If you have any side effects talk to your physician. This includes any possible side effects not listed in this brochure.

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/applications/forms/appendix-adverse-event-report-form.html for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Reference: 1. LUTATHERA® (lutetium (^{177}Lu) oxodotreotide) Product Monograph (Canada). February 4, 2019.

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Find a support organization

A support network of family, friends, and caregivers may help you through your treatment journey. In addition, support communities can provide you with information you may find helpful. Below is a list of support organizations that you and your caregivers may find helpful.

Canadian Neuroendocrine Tumour Society (CNETS)
www.cnets.ca

North American Neuroendocrine Tumor Society
www.nanets.net

International Neuroendocrine Cancer Alliance
www.incalliance.org

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