LUTATHERA®
(lutetium Lu 177 dotatate)
injection, for intravenous use

YOUR EDUCATIONAL GUIDE
for Your Treatment Journey With LUTATHERA

What is LUTATHERA?

LUTATHERA® (lutetium Lu 177 dotatate) is a prescription medicine used to treat adults and children aged 12 years and older with a type of cancer known as gastroenteropancreatic neuroendocrine tumors (GEP-NETs) that are positive for the hormone receptor somatostatin, including GEP-NETs in the foregut, midgut, and hindgut.

IMPORTANT SAFETY INFORMATION

What are some important things to know about the safety of LUTATHERA?

LUTATHERA is associated with some serious safety considerations and, in some cases, these may require your health care provider to adjust or stop your treatment. You should always follow your health care provider's instructions. Safety considerations include:

- **Radiation exposure:** Treatment with LUTATHERA will expose you to radiation, which can contribute to your long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. The radiation will be detectable in your urine for up to 30 days following administration of the drug. It is important to minimize radiation exposure to household contacts consistent with good radiation safety practices as advised by your health care provider.

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Please see additional Important Safety Information throughout this brochure and the Summary of Important Information on pages 16 and 17.

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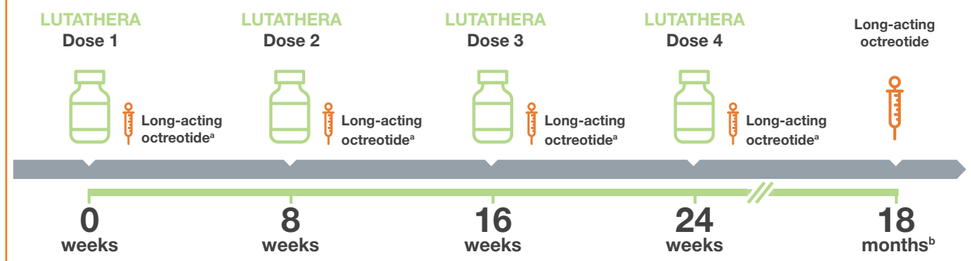
What Is LUTATHERA?

LUTATHERA is a prescription treatment for adults and children aged 12 years and older with a type of cancer known as gastroenteropancreatic neuroendocrine tumors (GEP-NETs) that are positive for the hormone receptor somatostatin.

LUTATHERA is given as an intravenous (IV) infusion.

- A full course of therapy consists of 4 doses of LUTATHERA. These doses will be 8 weeks apart. You and your health care professional will decide how many doses are right for you, as well as the time between each dose

Typical Treatment Regimen With LUTATHERA



Long-acting somatostatin analogues, also called SSAs, should be discontinued for at least 4 weeks prior to initiating LUTATHERA.

Short-acting octreotide may be given for symptomatic management during treatment with LUTATHERA, but must be withheld for at least 24 hours before each dose of LUTATHERA.

[a]During treatment with LUTATHERA, 30 mg of long-acting octreotide will be administered intramuscularly (IM) between 4 to 24 hours after each dose of LUTATHERA.

[b]You will continue to receive 30 mg of long-acting octreotide IM every 4 weeks for 18 months after starting treatment with LUTATHERA or until the time when your cancer may spread, grow, or get worse, or until your health care professional tells you to stop taking octreotide.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Bone marrow problems:** Treatment with LUTATHERA increases the risk of myelosuppression, a condition in which bone marrow activity is decreased, resulting in a drop in blood cell counts. You may experience blood-related side effects such as low red blood cells (anemia), low numbers of cells that are responsible for blood clotting (thrombocytopenia), and low numbers of white blood cells (neutropenia). Speak with your health care provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly.

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How Does LUTATHERA Work?

LUTATHERA is the first and only approved radioligand therapy (RLT) for GEP-NET, a medicine from a class of drugs called peptide receptor radionuclide therapy (PRRT).

- LUTATHERA is believed to work differently from most cancer medicines, with a 2-part approach that specifically targets and enters the cells that have somatostatin receptors, releasing energy in the form of radiation that damages them and nearby cells

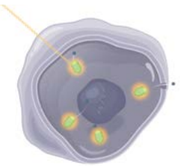
In other words, LUTATHERA is a "key" that connects with the "lock" (cells containing somatostatin receptors).

1. Attaches to Target Cells

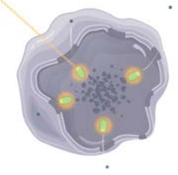
LUTATHERA is designed to contain a tumor-targeting part that attaches to cells with somatostatin receptors, including GEP-NET cancer cells.

Once it finds these cells, LUTATHERA is designed to bind to the somatostatin receptors located on the outside of the cells.

2. Enters Into Cell



After LUTATHERA binds to the somatostatin receptors, it is designed to enter into the cell.



Finally, LUTATHERA will deliver the radiation that causes damage to the targeted cells with the somatostatin receptor and neighboring cells.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Secondary bone marrow and blood cancers:** Other serious conditions that you may develop as a direct result of treatment with LUTATHERA include blood and bone marrow disorders known as secondary myelodysplastic syndrome and cancer known as acute leukemia. Your health care provider will routinely check your blood cell counts and tell you if they are too low or too high.

How May LUTATHERA Help?

In a clinical trial, 229 people with midgut NETs who received LUTATHERA in combination with 30 mg of long-acting octreotide were compared with those who received 60 mg of long-acting octreotide alone.

In the LUTATHERA group, the relative risk of the cancer getting worse or death was reduced by 79% compared with people treated with 60 mg of long-acting octreotide alone.

Reduced
the risk of cancer getting worse or death by
79%

More people treated with LUTATHERA had their tumors shrink compared with people treated with 60 mg of long-acting octreotide alone

13% of people
in the LUTATHERA with 30 mg of long-acting octreotide group

Partial response (tumors shrink)[a]:
12% (14 of 116 people)

Complete response (tumors disappear)[b]:
1% (1 of 116 people)

4% of people
in the 60 mg of long-acting octreotide group

Partial response (tumors shrink)[a]:
4% (4 of 113 people)

Complete response (tumors disappear)[b]:
0% (0 of 113 people)

[a]Tumors shrink by ≥30% from baseline.
[b]Tumors disappear and cancerous lymph nodes shrink to <10 mm. The disappearance of any measurable tumors does not necessarily mean that the cancer is completely gone.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Kidney problems:** Treatment with LUTATHERA will expose your kidneys to radiation and may impair their ability to work as normal. You may be at an increased risk for kidney problems after LUTATHERA treatment if you already have kidney impairment before treatment. In some cases, patients have experienced kidney failure after treatment with LUTATHERA. Your health care provider will provide you with an amino acid solution before, during, and after LUTATHERA to help protect your kidneys. You should stay well hydrated before, on the day of, and on the day after your treatment. You should urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Your doctor will monitor your kidney function and may withhold, reduce, or stop your LUTATHERA treatment accordingly.

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Before Starting Treatment

It's important to tell your health care professional everything about your disease and health status.

Health Information You May Want to Discuss

- Any medical conditions you may have
- Symptoms you may have
- Any changes in your daily habits
- If you have trouble controlling when you urinate or have a bowel movement
- All of the medicines you are taking, including over-the-counter medicines
- If you are trying to get pregnant, if you are already pregnant, or if you are breastfeeding

Make sure to let your health care professional know if you are taking either a type of medicine called a somatostatin analogue, also called an SSA, and/or glucocorticoids. If you are taking either, you might have to stop or change your treatment before and while receiving LUTATHERA.

- If you are a female who is able to get pregnant, use effective contraception during treatment with LUTATHERA and for 7 months after the last dose
- If you are a male with a female partner who is able to get pregnant, use effective contraception during treatment with LUTATHERA and for 4 months after the last dose
- Women should not breastfeed during treatment with LUTATHERA and for 2.5 months after the last dose

NETs, neuroendocrine tumors.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Liver problems:** In clinical studies of LUTATHERA, less than 1% of patients were reported to have tumor bleeding (hemorrhage), swelling (edema), or tissue damage (necrosis) to the liver. If you have tumors in your liver, you may be more likely to experience these side effects. Tell your health care provider right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, unusual tiredness, right upper stomach area (abdomen) pain, confusion, and/or swelling of the stomach area (abdomen). Your health care provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.
- **Allergic reactions:** Allergic reactions have occurred in people who were treated with LUTATHERA. Notify your health care provider if you develop symptoms of an allergic reaction. Seek emergency help right away for any serious allergic reactions. Symptoms may include trouble breathing or swallowing; raised bumps (hives); rash or itching; and swelling of the face, lips, tongue, throat, or arms.

What Is the Treatment Process With LUTATHERA?

1. Infusion day

You will go to the treatment center recommended by your health care professional to receive LUTATHERA. This is usually done in the nuclear medicine department.

Before you are given LUTATHERA: You will be given a medicine that is intended to help with vomiting or an upset stomach that you may experience because of the treatment.

30 minutes before you are given LUTATHERA: You will be given an amino acid solution through an IV infusion to help protect your kidneys. This infusion will last for the duration of your treatment with LUTATHERA and for at least 3 hours after it has been completed.

The infusion of LUTATHERA: It will take approximately 30 to 40 minutes and is given as an IV infusion.

2. After the infusion

Because treatment with LUTATHERA uses radiation, you will have to wait a while before you can leave the treatment center.

A health care professional will let you know when it's ok for you to leave the treatment center.

Within a day of receiving LUTATHERA: You will receive an injection of long-acting octreotide 30 mg after each infusion of LUTATHERA. Drink plenty of fluids and urinate frequently on the days you receive LUTATHERA and after.

Consider using this time with your health care professional to discuss any questions or concerns you may have regarding your treatment.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Hormonal gland problems (carcinoid crisis):** During your treatment you may experience certain symptoms that are related to hormones released from your cancer. These symptoms may include flushing, diarrhea, difficulty breathing (bronchospasm), and low blood pressure (hypotension), and may occur during or within the 24 hours after your first LUTATHERA treatment. Your health care provider will monitor you closely. Speak with your health care provider if you experience any of these signs or symptoms.

Please see additional Important Safety Information throughout this brochure and the Summary of Important Information on pages 16 and 17.

What Is the Treatment Process With LUTATHERA? (continued)

3. Your next infusion

You may receive LUTATHERA up to 3 more times after your first infusion.

These doses will be between 8 and 16 weeks apart, depending on how you may tolerate the medication.

You and your health care professional will decide how many doses and how long between each dose is right for you.

4. After your last dose

You may continue receiving long-acting octreotide 30 mg every 4 weeks for 18 months after starting treatment with LUTATHERA, until your cancer starts to spread or get worse, or until your health care professional tells you to stop taking octreotide.

LUTATHERA is a type of radiation therapy, so your health care professional will routinely do tests to check your liver, kidneys, and blood cells.

What are some important things to know about the safety of LUTATHERA? (continued)

- **Pregnancy warning:** Tell your health care provider if you are pregnant. LUTATHERA can harm your unborn baby. Females should use an effective method of birth control during treatment and for 7 months after the last dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment with LUTATHERA and for 4 months after the last dose.
- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your last dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testes or ovaries over the treatment period falls within the range of exposure in which temporary or permanent infertility may occur.

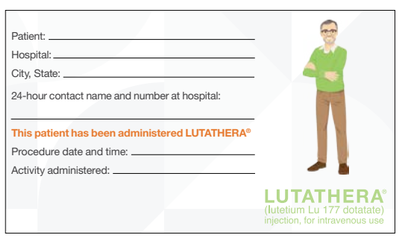
What to Expect When Receiving LUTATHERA

At the treatment center:

LUTATHERA is a nuclear medicine therapy. While you are taking LUTATHERA, you will be kept away from other patients in the hospital to limit their exposure. Your family members and caregivers may be with you during your treatment, but they may be asked to leave for 30 to 40 minutes while LUTATHERA is being given.

After receiving LUTATHERA:

Your nuclear medicine doctor will provide further instructions to help minimize radiation exposure to others. You should always follow your health care professional's instructions.



LUTATHERA treatment card:

Your nuclear medicine doctor may fill out a LUTATHERA treatment card and give it to you after treatment. This card will list your name, the amount of medicine that you received, and a hospital contact name and phone number. You should keep this card with you after your treatment, especially if you are traveling through an airport.

You should drink plenty of fluids on the day before, on the day of, and on the day after you receive LUTATHERA. Generally, the more you urinate, the faster you will get rid of the excess radiation from your body.

What are the most common side effects of LUTATHERA?

The most common and most serious side effects of LUTATHERA include decreased blood cell counts, increased liver enzymes, vomiting, nausea, increased blood glucose, and decreased blood potassium levels.

Talk to your doctor if you experience any of these side effects. There are other possible side effects of LUTATHERA. For more information and to learn more about LUTATHERA, talk to your doctor or health care provider.

Adverse reactions observed in children aged 12 years and older were similar to those observed in adults treated with LUTATHERA.

Please see additional Important Safety Information throughout this brochure and the Summary of Important Information on pages 16 and 17.

Helpful Considerations While on Treatment With LUTATHERA

Minimizing radiation exposure to those around you: Your health care professional will provide you with information to help minimize radiation exposure to those around you while you are on treatment with LUTATHERA. Here are some other considerations to keep in mind. Guidelines for minimizing radiation exposure may vary depending on the health care professional and/or facility.

Using the toilet

- 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 and flush twice
- Wash your hands every time you use the toilet

Showering

- Daily showering is recommended for at least the first few days after receiving LUTATHERA

Caretaker

- If a caretaker helps you in the bathroom, they should wear disposable gloves for the first few days after you are given LUTATHERA

It is important to follow the safety guidelines provided to you by your health care professional or treatment facility.

What other medicines may interact with LUTATHERA?

Tell your health care provider if you are taking any other medications. You should stop taking your long-acting somatostatin analogue at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogues up to 24 hours before your LUTATHERA treatment.

Potential Side Effects

All prescription medications come with safety considerations. Some considerations you should be aware of before starting LUTATHERA relate to:

- Radiation exposure
- Bone marrow problems
- Secondary bone marrow and blood cancers
- Kidney problems
- Liver problems
- Allergic reactions
- Hormonal gland problems (carcinoid crisis)
- Embryo-fetal toxicity
- Infertility

What side effects could I experience with LUTATHERA?

LUTATHERA may cause side effects. Some of these side effects can be serious, and your health care professional may need to adjust or stop your treatment if you experience any of these. You should always follow the instructions from your health care professional.

In clinical trials, the most common grade 3/4 (severe) adverse reactions occurring with a greater frequency among patients receiving LUTATHERA included:

- Decreased blood cell counts
- Increased liver enzymes
- Vomiting
- Nausea
- Increased blood glucose levels
- Decreased blood potassium levels

Talk to your health care professional if you experience any side effects. There are other possible side effects of LUTATHERA. For more information and to learn more about LUTATHERA, talk to your health care professional.

Please see additional warnings in this brochure and in the full Prescribing Information regarding pregnancy, breastfeeding, and use of birth control.

Talk to your health care professional if you have any of these side effects or experience any other side effects associated with LUTATHERA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information for LUTATHERA.

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Novartis Patient Support™

Novartis Patient Support provides dedicated, ongoing help and resources starting when you sign up.

Available support offered by Novartis Patient Support includes:

Live Support | **Insurance Support** | **Savings Support**

A dedicated team is just a phone call away

Our Novartis Patient Support Team can help provide information on benefits verification and prior authorizations. They are available to help you, your health care provider, and your care team.

Co-pay savings start when you sign up

We understand that paying for treatment, including co-pays, can sometimes be a burden. A co-pay is the amount of money your insurance company asks you to pay for an appointment, procedure, or medication.

Novartis Patient Support Co-Pay Savings is available to patients with private insurance (or insurance provided by an employer or purchased individually) who meet specific eligibility criteria. Once you sign up for Novartis Patient Support, you will be considered for co-pay savings.

$25 CO-PAY*

If you have private insurance, you may pay as little as $25 per dose.*

To start the process, check with your health care provider or care team to make sure your Enrollment Form is completed, signed, and submitted.

*Limitations apply. Valid only for those patients with commercial insurance. Not valid under Medicare or any other federal or state program. Offer subject to a maximum benefit per course of treatment. See complete Terms and Conditions in the Enrollment Forms for details.

See the following page for enrollment details.

Additional financial support may be available for patients without private insurance

If you don't have private or government insurance (for example, Medicare or Medicaid insurance), you may be eligible for other savings support options. For more information call 1-888-NOW-NOVA (1-888-669-6682).

For more information about Novartis Patient Support, call 1-844-638-7222

Novartis Patient Support (continued)

Enrolling in Novartis Patient Support

1 Ask your health care provider or care team about getting started with Novartis Patient Support

Staying on track with treatment is easier with reliable support. Novartis Patient Support helps you get started and stay on treatment.

2 Work with your health care provider or care team to complete and sign the Enrollment Form

Fill out all required sections of the Enrollment Form with your health care provider or care team. Then, sign the form to authorize your enrollment in Novartis Patient Support.

3 Connect with your Novartis Patient Support Team

A dedicated Novartis Patient Support Team member will connect with you and your health care provider or care team to confirm sign up and provide additional information about options that match your treatment plan.

For more information about Novartis Patient Support, call 1-844-638-7222

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Find Support Organizations for GEP-NET

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.

Carcinoid Cancer Foundation (CCF)
333 Mamaroneck Avenue #492
White Plains, NY 10605
1-888-722-3132
www.carcinoid.org

Healing NET Foundation
200 Hill Avenue, Suite 4
Nashville, TN 37210
1-615-369-6463
www.thehealingnet.org

Learn Advocate Connect Neuroendocrine Tumor Society (LACNETS)
info@lacnets.org
www.lacnets.org

Neuroendocrine Cancer Awareness Network (NCAN)
3074 Brookchase Boulevard
Fort Mill, SC 29707
1-866-850-9555
help@netcancerawareness.org
netcancerawareness.org

Northern California CarciNET Community (NorCal CarciNET)
946 North Ripon Road
Ripon, CA 95366
norcalcarcinet.org

Provided for informational purposes only. This is not intended to be a recommendation or endorsement of any organization.

Summary of Important Information

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LUTATHERA is associated with some serious safety considerations and, in some cases, these may require your health care provider to adjust or stop your treatment. You should always follow your health care provider's instructions. Safety considerations include:

- **Radiation exposure:** Treatment with LUTATHERA will expose you to radiation, which can contribute to your long-term radiation exposure. Overall radiation exposure is associated with an increased risk for cancer. The radiation will be detectable in your urine for up to 30 days following administration of the drug. It is important to minimize radiation exposure to household contacts consistent with good radiation safety practices as advised by your health care provider.
- **Bone marrow problems:** Treatment with LUTATHERA increases the risk of myelosuppression, a condition in which bone marrow activity is decreased, resulting in a drop in blood cell counts. You may experience blood-related side effects such as low red blood cells (anemia), low numbers of cells that are responsible for blood clotting (thrombocytopenia), and low numbers of white blood cells (neutropenia). Speak with your health care provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath, or increased bleeding or bruising. Your health care provider may need to adjust or stop your treatment accordingly.
- **Secondary bone marrow and blood cancers:** Other serious conditions that you may develop as a direct result of treatment with LUTATHERA include blood and bone marrow disorders known as secondary myelodysplastic syndrome and cancer known as acute leukemia. Your health care provider will routinely check your blood cell counts and tell you if they are too low or too high.
- **Kidney problems:** Treatment with LUTATHERA will expose your kidneys to radiation and may impair their ability to work as normal. You may be at an increased risk for kidney problems after LUTATHERA treatment if you already have kidney impairment before treatment. In some cases, patients have experienced kidney failure after treatment with LUTATHERA. Your health care provider will provide you with an amino acid solution before, during, and after LUTATHERA to help protect your kidneys. You should stay well hydrated before, on the day of, and on the day after your treatment. You should urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Your doctor will monitor your kidney function and may withhold, reduce, or stop your LUTATHERA treatment accordingly.
- **Liver problems:** In clinical studies of LUTATHERA, less than 1% of patients were reported to have tumor bleeding (hemorrhage), swelling (edema), or tissue damage (necrosis) to the liver. If you have tumors in your liver, you may be more likely to experience these side effects. Tell your health care provider right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or the whites of the eyes (jaundice), unusual darkening of the urine, unusual tiredness, right upper stomach area (abdomen) pain, confusion, and/or swelling of the stomach area (abdomen). Your health care provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.

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Summary of Important Information (continued)

What are some important things to know about the safety of LUTATHERA? (continued)

- **Allergic reactions:** Allergic reactions have occurred in people who were treated with LUTATHERA. Notify your health care provider if you develop symptoms of an allergic reaction. Seek emergency help right away for any serious allergic reactions. Symptoms may include trouble breathing or swallowing; raised bumps (hives); rash or itching; and swelling of the face, lips, tongue, throat, or arms.
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- **Pregnancy warning:** Tell your health care provider if you are pregnant. LUTATHERA can harm your unborn baby. Females should use an effective method of birth control during treatment and for 7 months after the last dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment with LUTATHERA and for 4 months after the last dose.
- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your last dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testes or ovaries over the treatment period falls within the range of exposure in which temporary or permanent infertility may occur.

What are the most common side effects of LUTATHERA?

The most common and most serious side effects of LUTATHERA include decreased blood cell counts, increased liver enzymes, vomiting, nausea, increased blood glucose, and decreased blood potassium levels.

Talk to your doctor if you experience any of these side effects. There are other possible side effects of LUTATHERA. For more information and to learn more about LUTATHERA, talk to your doctor or health care provider.

Adverse reactions observed in children aged 12 years and older were similar to those observed in adults treated with LUTATHERA.

What other medicines may interact with LUTATHERA?

Tell your health care provider if you are taking any other medications. You should stop taking your long-acting somatostatin analogue at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogues up to 24 hours before your LUTATHERA treatment.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information for LUTATHERA.

Want to find out more about LUTATHERA? Visit us at:

Facebook.com/LUTATHERA

VISIT LUTATHERA.COM

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(lutetium Lu 177 dotatate)
injection, for intravenous use

Novartis Pharmaceuticals Corporation
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