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

AN EDUCATIONAL GUIDE

For Your Treatment Journey With LUTATHERA

What is LUTATHERA?

LUTATHERA® (lutetium Lu 177 dotatate) is a prescription medicine used to treat adults 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 healthcare provider to adjust or stop your treatment. You should always follow your healthcare 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 healthcare provider.

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Please see Important Safety Information throughout and on pages 15 and 16 and full Prescribing Information.

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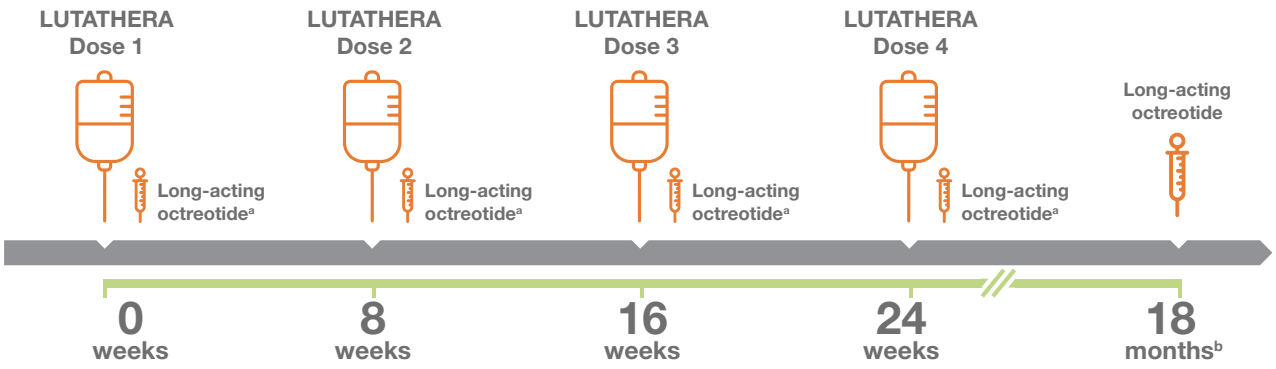
What Is LUTATHERA?

LUTATHERA® (lutetium Lu 177 dotatate) is a prescription treatment for adults with a type of cancer known as gastroenteropancreatic neuroendocrine tumor (GEP-NET) that has somatostatin hormone receptors.

LUTATHERA is given as an intravenous (IV) infusion.

- A full course of therapy consists of 4 doses of LUTATHERA. These doses will be between 8 and 16 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 analogs, 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 between 4 to 24 hours after each dose of LUTATHERA.

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 healthcare provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath or increased bleeding or bruising. Your healthcare provider may need to adjust or stop your treatment accordingly.

How Does LUTATHERA Work?

LUTATHERA® (lutetium Lu 177 dotatate) is the first and only approved radioligand therapy (also known as RLT) for GEP-NET, a medicine from a class of drugs called peptide receptor radionuclide therapy (also known as 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

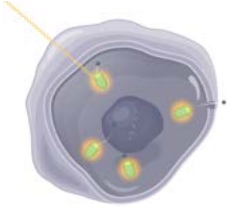
In other words, LUTATHERA is a "key" that connects with the "lock" (cells containing somatostatin receptors).

1. ATTACHES TO TARGET CELLS

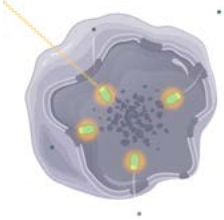
LUTATHERA is designed to contain a tumor-targeting part that attaches to cells with somatostatin receptors, including GEP-NET cancer cells.

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.

Mechanism of Action of LUTATHERA

LUTATHERA | SOMATOSTATIN RECEPTOR TYPE 2 | GEP-NET CELL | NUCLEUS

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 healthcare provider will routinely check your blood cell counts and tell you if they are too low or too high.

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Please see Important Safety Information throughout and on pages 15 and 16 and full Prescribing Information.

How May LUTATHERA Help?

In a clinical trial, 229 people with midgut NETs who received LUTATHERA® (lutetium Lu 177 dotatate) 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 risk of the cancer getting worse or death was reduced by 79% compared with people treated with 60 mg of long-acting octreotide alone.

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 plus 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 by <10 mm. The disappearance of any measurable tumors does not necessarily mean that the cancer is completely gone.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 healthcare 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, during, and after your treatment. You should urinate frequently during and 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 analog, also called an SSA, and/or corticosteroids. If you are taking either, you might have to stop or change your treatment before and while receiving LUTATHERA® (lutetium Lu 177 dotatate).

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

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. Signs that you may be experiencing liver damage include increases in blood markers called ALT, AST and GGT. Your healthcare provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.
- **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 healthcare provider will monitor you closely. Speak with your healthcare provider if you experience any of these signs or symptoms.

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® (lutetium Lu 177 dotatate). 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 amino acids 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: 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 okay for you to leave the treatment center.

Within a day of receiving LUTATHERA: You will be given an injection of long-acting octreotide 30 mg. 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- **Pregnancy warning:** Tell your healthcare 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 final dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment and for 4 months after the final dose of LUTATHERA.

What Is the Treatment Process With LUTATHERA? (Continued)

3. Your next infusion

You may receive LUTATHERA® (lutetium Lu 177 dotatate) 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 up to 18 months since starting treatment with LUTATHERA, or until your cancer starts to spread or get worse.

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your final dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testis or ovaries over the treatment period falls in the range of exposure where temporary or permanent infertility may occur.

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Please see Important Safety Information throughout and on pages 15 and 16 and full Prescribing Information.

What to Expect When Receiving LUTATHERA

At the treatment center:

LUTATHERA® (lutetium Lu 177 dotatate) 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 days you receive LUTATHERA and after. Generally, the more you urinate, the faster you will get rid of the radiation from your body.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are the most common side effects of LUTATHERA?

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

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 healthcare provider.

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Helpful Considerations While on Treatment With LUTATHERA

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® (lutetium Lu 177 dotatate). 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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

What other medicines may interact with LUTATHERA?

Tell your healthcare provider if you are taking any other medications. Somatostatin analogs and corticosteroids may affect how your LUTATHERA treatment works. You should stop taking your long-acting somatostatin analog at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogs up to 24 hours before your LUTATHERA treatment. Avoid repeated high doses of glucocorticosteroids during treatment with LUTATHERA.

Potential Side Effects

What are some important things to know about LUTATHERA?

All prescription medications come with safety considerations. Some considerations you should be aware of before starting LUTATHERA® (lutetium Lu 177 dotatate) relate to:

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

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:

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

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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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AAA PatientCONNECT™

Go to www.aaapatientconnect.com for more information about AAA PatientCONNECT™

AAA **Patient**CONNECT™ provides services to facilitate your access to LUTATHERA® (lutetium Lu 177 dotatate) treatment. This may include:

Patient Financial Assistance

- Commercial patient copay assistance

Other Assistance

- Insurance benefits verification
- Prior authorization eligibility check
- Financial assistance for eligible patients

Underinsured or Uninsured Financial Assistance

If a patient does not have insurance, is underinsured, has insurance yet still cannot afford, or otherwise cannot afford their LUTATHERA treatment there may be an option for them. All patients must enroll through AAAPC at aaapatientconnect.com or by calling 1-844-638-7222.

For more information, contact AAA **Patient**CONNECT™ at 1-844-638-7222.

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AAA PatientCONNECT™ (Continued)

AAA **Patient**CONNECT™ may provide copay assistance for LUTATHERA® (lutetium Lu 177 dotatate) treatment to patients who have commercial insurance and meet certain eligibility criteria.*

You may qualify for assistance if:

- You have commercial insurance and certify that you do not have any government insurance
- Your LUTATHERA treatment is being provided in an outpatient setting
- You are a permanent resident of the United States, including any of its territories, or the District of Columbia

Copay assistance is not available through the AAA **Patient**CONNECT™ program for patients who have public or government insurance, such as insurance available as through Medicare, Department of Veterans Affairs, or the Department of Defense. AAA **Patient**CONNECT™ is not an insurance program and is not a substitute for medical insurance.

*Eligibility restrictions may apply. For full terms and conditions, please call AAA **Patient**CONNECT™ at 1-844-638-7222. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the copayment support provided under this program, e.g. copay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law or restricted.

Enrolling in Copay Assistance

To enroll in financial assistance for commercial insurance, your healthcare provider must submit a completed and signed AAA **Patient**CONNECT™ Program Enrollment Form on your behalf. AAA **Patient**CONNECT™ Program Enrollment Forms are available online at www.aaapatientconnect.com.

By signing the AAA **Patient**CONNECT™ Program Enrollment Form, you agree that, if approved for the copay assistance program, all copay assistance funds distributed will be used only for the cost of LUTATHERA®.

Receiving Copay Financial Assistance

Upon approval, AAA **Patient**CONNECT™ will send you an approval letter and outline of the copay assistance funds that are available for your treatment.

Proof of LUTATHERA® treatment and claims processed must be submitted to AAA **Patient**CONNECT™ for distribution of copay assistance funds.

Upon receipt of required documents, copay assistance funds will be processed.

For more information, contact AAA **Patient**CONNECT™ at 1-844-638-7222.

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

Los Angeles Carcinoid 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
www.netcancerawareness.org

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

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

Important Safety Information

What is LUTATHERA?

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- **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 healthcare 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 healthcare provider if you experience any signs or symptoms of infection, fever, chills, dizziness, shortness of breath or increased bleeding or bruising. Your healthcare provider may need to adjust or stop your treatment accordingly.
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- **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 healthcare 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, during, and after your treatment. You should urinate frequently during and 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. Signs that you may be experiencing liver damage include increases in blood markers called ALT, AST and GGT. Your healthcare provider will monitor your liver using blood tests and may need to withhold, reduce, or stop your LUTATHERA treatment accordingly.

Important Safety Information (Continued)

IMPORTANT SAFETY INFORMATION (CONTINUED)

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® (lutetium Lu 177 dotatate) treatment. Your healthcare provider will monitor you closely. Speak with your healthcare provider if you experience any of these signs or symptoms.
- **Pregnancy warning:** Tell your healthcare 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 final dose of LUTATHERA. Males with female partners should use an effective method of birth control during treatment and for 4 months after the final dose of LUTATHERA.
- **Breastfeeding warning:** You should not breastfeed during treatment with LUTATHERA and for 2.5 months after your final dose of LUTATHERA.
- **Fertility problems:** Treatment with LUTATHERA may cause infertility. This is because radiation absorbed by your testis or ovaries over the treatment period falls in the range of exposure where 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: vomiting, nausea, decreased blood cell counts, increased liver enzymes, decreased blood potassium levels, and increased blood glucose.

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 healthcare provider.

What other medicines may interact with LUTATHERA?

Tell your healthcare provider if you are taking any other medications. Somatostatin analogs and corticosteroids may affect how your LUTATHERA treatment works. You should stop taking your long-acting somatostatin analog at least 4 weeks before LUTATHERA treatment. You may continue taking short-acting somatostatin analogs up to 24 hours before your LUTATHERA treatment. Avoid repeated high doses of glucocorticosteroids during treatment 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.

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