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

LUTATHERA:
Your Trusted RLT in SSTR+ GEP-NETs

The first and only FDA-approved RLT in SSTR+ GEP-NETs, with **>18,000 patients treated over 7 years**[1-3,*]

*Internal data tracking as of May 2025.

FDA, US Food and Drug Administration; GEP-NETs, gastroenteropancreatic neuroendocrine tumors; RLT, radioligand therapy; SSTR+, somatostatin receptor-positive.

INDICATION

LUTATHERA® (lutetium Lu 177 dotatate) is indicated for the treatment of adult and pediatric patients aged 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Radiation Exposure:** Treatment with LUTATHERA contributes to a patient's overall long-term cumulative radiation exposure and is associated with an increased risk for cancer. Radiation can be detected in the urine for up to 30 days following LUTATHERA administration. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with LUTATHERA consistent with institutional good radiation safety practices, patient management procedures, Nuclear Regulatory Commission patient release guidance, and instructions to the patient for follow-up radiation protection at home.

Please see additional Important Safety Information throughout and full Prescribing Information.

NOVARTIS

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Please see additional Important Safety Information throughout and full Prescribing Information.

We are continuously improving our production processes for faster on-time delivery

99% on-time delivery for all LUTATHERA orders[4,*]

~63,000 orders shipped from launch to date[5,†]

There are 2 state-of-the-art manufacturing sites for LUTATHERA in the United States (New Jersey and Indiana), with planned expansion to California to support all West Coast needs.

There are over 18,000 patients treated with LUTATHERA to date[2,‡]

Our latest implementation of no carrier-added lutetium (NCA Lu 177) is aimed at simplifying and improving postinfusion waste management protocols at individual treatment sites.[6]

- The efficacy and safety of LUTATHERA is not expected to be impacted by the switch from carrier-added to NCA Lu 177[6]

Get product ordering support

Product ordering support is available by calling **1-844-367-3222**, Monday through Friday, 8:00 AM to 8:00 PM ET, excluding holidays.

*Year-to-date data (since January 1).
†US commercial orders only. Data as of May 2025.
‡Internal data tracking as of May 2025.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Myelosuppression:** In the NETTER-1 clinical trial, myelosuppression occurred more frequently in patients receiving LUTATHERA with long-acting octreotide compared with patients receiving high-dose long-acting octreotide (all grades/grade 3/4): anemia (81%/0 vs 54%/1%), thrombocytopenia (53%/1% vs 17%/0), and neutropenia (26%/3% vs 11%/0). In NETTER-1, platelet nadir occurred at a median of 5.1 months following the first dose.

Please see additional Important Safety Information throughout and full Prescribing Information.

LUTATHERA treatment sites are available nationwide

There are over 440 LUTATHERA treatment sites across the United States[7,*]

Find treatment sites near you

You can search by name of the practice, city, state, or ZIP code. Please check back regularly, as this list will be periodically updated with newly certified locations.

Interested in becoming a treatment site?

Call Novartis Patient Support™ at **1-844-638-7222**, Monday through Friday, 8:00 AM to 8:00 PM ET, excluding holidays.

*As of June 2025.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Myelosuppression (continued):** Of the 59 patients who developed thrombocytopenia, 68% had platelet recovery to baseline or normal levels. The median time to platelet recovery was 2 months. Fifteen of the 19 patients in whom platelet recovery was not documented had post-nadir platelet counts. Among these 15 patients, 5 improved to grade 1, 9 to grade 2, and 1 to grade 3. Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of myelosuppression.

Please see additional Important Safety Information throughout and full Prescribing Information.

LUTATHERA is accessible for most insured patients*

76% of patients had coverage for LUTATHERA as of January 2025[8]

The other 24% are on plans that do not have published policies and/or cases may be decided on an individual basis. Follow up with the patient's plan to determine coverage.

85% of covered patients paid $0 out of pocket per infusion[9]

A review of claims data between Q1 2023 and Q2 2024 indicated that approximately 85% of patients paid $0 for the product. For remaining patients, the out-of-pocket cost for the product varies and may be as high as the total cost of the product. Additional out-of-pocket costs may be incurred related to treatment, including, but not limited to, administration fees.

~2 days

Average benefit verification response time†

Resources to assist with patient access

Download forms that can assist with coverage, including a LUTATHERA sample letter of appeal and co-pay reimbursement guides for both health care professionals and patients.

*The information provided in this communication is not a guarantee of coverage and patient out-of-pocket costs may vary. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims and will vary.
†Primary plans only; an additional 1 to 2 days if secondary plan coverage review is required.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Secondary Myelodysplastic Syndrome and Leukemia:** In NETTER-1, with a median follow-up time of 76 months in the main study, myelodysplastic syndrome (MDS) was reported in 2.3% of patients receiving LUTATHERA with long-acting octreotide compared with no patients receiving high-dose long-acting octreotide. In ERASMUS, a phase 2 clinical study, 16 patients (2.0%) developed MDS and 4 (0.5%) developed acute leukemia.

Please see additional Important Safety Information throughout and full Prescribing Information.

Novartis Patient Support™: A dedicated team for you and your patients

We provide support throughout your patient's journey with:

Insurance & Reimbursement

Support includes:

- Benefits verification
- Prior authorization requirements
- Appeals support
- Billing, coding, and reimbursement education

Financial Support

Eligible patients may pay as little as $0* per dose. Enrollment is required to determine eligibility and participation.

Acquisition

Support includes:

- New treating site onboarding and access to ordering platform
- Real-time delivery tracking

Patient Education

Live 1-on-1 support is available for patients starting treatment. Our Patient Navigators can help answer the most common treatment questions.

Call Novartis Patient Support

For any questions you may have, call Novartis Patient Support at **1-844-638-7222**, Monday through Friday, 8:00 AM to 8:00 PM ET, excluding holidays.

*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 Start Form for details.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Secondary Myelodysplastic Syndrome and Leukemia (continued):** The median time to onset was 29 months (range, 9-45 months) for MDS and 55 months (range, 32-125 months) for acute leukemia.

Please see additional Important Safety Information throughout and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Renal Toxicity:** In ERASMUS, 8 patients (<1%) developed renal failure 3 to 36 months following LUTATHERA. Two of these patients had underlying renal impairment or risk factors for renal failure (eg, diabetes or hypertension) and required dialysis. Administer the recommended amino acid solution before, during, and after LUTATHERA to decrease the reabsorption of lutetium Lu 177 dotatate through the proximal tubules and decrease the radiation dose to the kidneys. Advise patients to hydrate and to urinate frequently before, on the day of, and on the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of renal toxicity. Patients with baseline renal impairment may be at increased risk of toxicity due to increased radiation exposure; perform more frequent assessments of renal function in patients with baseline mild or moderate impairment. LUTATHERA has not been studied in patients with baseline severe renal impairment (creatinine clearance <30 mL/min) or those with end-stage renal disease.
- **Hepatotoxicity:** In ERASMUS, 2 patients (<1%) were reported to have hepatic tumor hemorrhage, edema, or necrosis, with 1 patient experiencing intrahepatic congestion and cholestasis. Patients with hepatic metastasis may be at increased risk of hepatotoxicity due to radiation exposure. Monitor transaminases, bilirubin, serum albumin, and the international normalized ratio during treatment. Withhold dose, reduce dose, or permanently discontinue LUTATHERA based on the severity of hepatotoxicity.
- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, occurred in patients treated with LUTATHERA. Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis, during and following LUTATHERA administration for a minimum of 2 hours in a setting in which cardiopulmonary resuscitation medication and equipment are available. Discontinue the infusion upon the first observation of any signs or symptoms consistent with a severe hypersensitivity reaction and initiate appropriate therapy. Premedicate patients with a history of grade 1/2 hypersensitivity reactions to LUTATHERA before subsequent doses. Permanently discontinue LUTATHERA in patients who experience grade 3/4 hypersensitivity reactions.
- **Neuroendocrine Hormonal Crisis:** Neuroendocrine hormonal crises, manifesting with flushing, diarrhea, bronchospasm, and hypotension, occurred in <1% of patients in ERASMUS and typically occurred during or within 24 hours following the initial LUTATHERA dose. Two (<1%) patients were reported to have hypercalcemia. Monitor patients for flushing, diarrhea, hypotension, bronchoconstriction, or other signs and symptoms of tumor-related hormonal release. Administer intravenous somatostatin analogues, fluids, corticosteroids, and electrolytes as indicated.

Please see full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Embryo-Fetal Toxicity:** LUTATHERA can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to initiating LUTATHERA. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LUTATHERA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with LUTATHERA and for 4 months after the last dose.
- **Risk of Infertility:** LUTATHERA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative LUTATHERA dose falls within the range in which temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The most common grade 3/4 adverse reactions (≥4% with a higher incidence in the LUTATHERA arm) observed in NETTER-1 were lymphopenia (44%), increased gamma-glutamyl transferase (20%), vomiting (7%), nausea (5%), increased aspartate aminotransferase (5%), increased alanine aminotransferase (4%), hyperglycemia (4%), and hypokalemia (4%).

In ERASMUS, the following serious adverse reactions have been observed with a median follow-up time of >4 years after treatment with LUTATHERA: myelodysplastic syndrome (2%), acute leukemia (1%), renal failure (2%), hypotension (1%), cardiac failure (2%), myocardial infarction (1%), and neuroendocrine hormonal crisis (1%). Patients should be counseled and monitored in accordance with the LUTATHERA Prescribing Information.

Adverse reactions observed in pediatric patients were similar to those observed in adults treated with LUTATHERA.

DRUG INTERACTIONS

Discontinue long-acting somatostatin analogues at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose.

SPECIFIC POPULATIONS

Lactation: Advise patients not to breastfeed during LUTATHERA treatment.

Please see full Prescribing Information.

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

LUTATHERA: Your Trusted RLT in SSTR+ GEP-NETs

>18,000
patients treated since approval in 2018[2,3]

>7 YEARS
of RLT experience in the GEP-NET space[3]

76%
of insured patients had treatment coverage[8]

85%
of covered patients paid $0 out of pocket per infusion[9]

Make the decision to START LUTATHERA early for your eligible patients

Download the Start Form
and then fax the completed form to Novartis Patient Support at 1-844-638-7329. Registration is required.

Visit the treatment site locator
for the most up-to-date list of LUTATHERA treatment centers near your patients.

References: 1. Lutathera. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. LUTATHERA ROME extract. Novartis Pharmaceuticals Corp; May 2025. **3.** US Food and Drug Administration. FDA approves lutetium Lu 177 dotatate for treatment of GEP-NETS. Updated January 26, 2018. Accessed June 1, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-lutetium-lu-177-dotatate-treatment-gep-nets **4.** Data on file. US KPI Review. Novartis Pharmaceuticals Corp; 2025. **5.** Data on file. LUTATHERA ROME extract. Novartis Pharmaceuticals Corp; May 2025. **6.** Data on file. Commercial Q&A. Novartis Pharmaceuticals Corp; 2025. **7.** Data on file. LUTATHERA ROME extract. Novartis Pharmaceuticals Corp; June 2025. **8.** Data on file. MMIT Data. Novartis Pharmaceuticals Corp; May 2025. **9.** Data on file. IQVIA Pluvicto & Lutathera Reimbursement Landscape. Novartis Pharmaceuticals Corp; 2025.

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