^{177}LU-DOTATATE APPENDIX 1: SAMPLE COMPOUNDING FORMULA

Product: L-lysine 1.25% and L-arginine 1.25% IV solution
Volume: 1,000 mL

Compounding Ingredient	Amount	Tech Check	RPh Check
L-lysine HCl powder	15.7 g		
L-arginine powder	15.2 g		
Sterile water for irrigation	98 mL		
Sterile water for injection	743 mL		
0.9% NaCl for injection	140 mL		

Supplies:

1. 500 mL beaker x1
2. 0.2 micron filter x2
3. 60 mL syringe x2

Instructions for Preparation:

1. Use aseptic technique.
2. Insert 743 mL of sterile water and 140 mL of 0.9% NaCl in a 1,000 mL bag.
3. Add 98 mL of sterile water in a 500 mL beaker.
4. Weigh 15.7 grams of L-lysine powder and 15.2 grams of L-arginine powder.
5. Dissolve in a beaker with the 98 mL of water.
6. After dissolution, draw up 60 mL using 60 mL syringes x 2.
7. In laminar flow hood, attach 0.2 micron filter onto each syringe.
8. Filter-sterilize the solution into the 1000 mL bag with 743 mL of water and 140 mL of sodium chloride.
9. Verify that product is a clear solution.
10. Foil seal bag and label with patient-specific label.
11. Follow procedure for filter integrity testing per institutional protocol.
12. Refrigerate for up to 24 hours.

^{177}LU-DOTATATE APPENDIX 2: SAMPLE ORDER SET

TREATMENT PARAMETERS

Laboratory:

- Creatinine clearance ≥ 40 mL/min
- Serum creatinine ≤ 1.7 mg/dL
- Hemoglobin ≥ 5 mmol/L
- WBC ≥2,000/mm^3
- Platelets ≥ 75,000
- Total bilirubin < 3x ULN
- Serum albumin > 3 g/dL or serum albumin ≤ 3 with a normal PT

Exclusions:

- Pregnancy
- Anuria
- Octreotide (short-acting) administered within the past 24 hours
- Octreotide (long-acting) administered within the past 4 weeks

CHEMOTHERAPY ORDERS

Lutetium Lu 177 dotatate (Lutathera) 7.4 GBq (flat dose) to be infused with 500 mL NS at 50 to 100 mL/hr for 5 to 10 minutes, then 200 to 300 mL/hr for an additional 25 to 30 minutes

HYDRATION

Amino acid solution (25 g L-arginine and 25 g L-lysine/1000 mL) 2000 mL IV to be infused over 4 hours starting 30 minutes prior to administering Lutetium Lu 177 dotatate

Sodium chloride 0.9% 100 mL to be infused over 10 minutes after administering Lutetium Lu 177 dotatate

SUPPORTIVE CARE

Antiemetics:

- *Dexamethasone* 4 mg PO 30 minutes prior to amino acid infusion
- *Fosaprepitant* 150 mg IV 30 minutes prior to amino acid infusion
- *Ondansetron* 16 mg PO 30 minutes prior to amino acid infusion
- *Lorazepam* 0.5 mg PO/IV every 6 hours as needed
- *Prochlorperazine* 10 mg PO/IV every 6 hours as needed
- *Optional (per discretion of treating provider): Olanzapine* 10 mg PO 30 minutes prior to amino acid infusion

Others:

- *Furosemide* 20 mg PO/IV once as needed
- *Octreotide* 100 mcg SQ every 8 hours as needed for neurohormonal crisis
- *Octreotide* LAR 30 mg IM once 4 to 24 hours after administration of Lutetium Lu 177 Dotatate

TAKE-HOME MEDICATIONS

Octreotide 100 mcg SQ every 8 hours as needed for neurohormonal crisis

Ondansetron 8 mg PO daily on Day 2 and 3

Lorazepam 0.5 mg PO every 6 hours as needed

Prochlorperazine 10 mg PO every 6 hours as needed

Optional (per discretion of treating provider): Olanzapine 10 mg PO daily on Day 2 and 3

LABS

Complete blood count (WBC/Hgb/PLTs/MCV): Baseline and on Day 1, 28, and 42 of each cycle

Complete metabolic panel (SCr/TBili/albumin): Baseline and on Day 1, 28, and 42 of each cycle

Cancer antigen: Baseline and on Day 1 of each cycle

VITAL SIGNS

Heart rate and blood pressure

- Prior to amino acid infusion
- Prior to Lutetium Lu 177 Dotatate infusion
- After Lutetium Lu 177 Dotatate infusion

^{177}LU-DOTATATE APPENDIX 3: SAMPLE PATIENT CONSENT

Lutetium lu 177 dotatate (Lutathera®)

I understand that I have a somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumor. My primary Oncology physician is _____. My physician has discussed that the purpose of this treatment is curative, meaning that the cancer disappears and does not return.

I authorize Dr. _____, and/or such other health care professionals at _____ _____, to administer Lutetium lu 177 dotatate (Lutathera®) 7.4 GBq IV once every 8 weeks for a total of 4 doses.

I acknowledge that I have been given a handout containing detailed information about warnings and side effects of the medication. I understand that I may experience:

- Nausea/vomiting
- Abdominal pain/diarrhea
- Fatigue
- Swelling of the extremities
- Myelosuppression (low blood counts)
- Hyperglycemia (high blood sugar)
- Nephrotoxicity (kidney damage)
- Hyperuricemia (high uric acid)
- Hypocalcemia/kalemia (low calcium and potassium)
- Hepatotoxicity (liver damage)

Other side effects that are less common but may still occur include:

- Secondary cancers
- Neuroendocrine hormonal crises (tumor-hormone release)
- Back pain
- Headache/dizziness
- Alopecia

I also understand that I could have side effects from my treatment that have not been discussed with me or are not listed in these forms. Each patient can respond differently and may have side effects that are not reported by others. I understand that I will be monitored for side effects during the course of my treatment.

This treatment will require the need to have an intravenous (IV) line inserted into my body, which will allow medicine to be delivered directly into my veins. This could be with a short-term type of IV or a longer-term type of catheter. In addition, this treatment may require the administration of the following medications as well:

- Amino acid infusion to protect my kidneys
- Anti-nausea infusion and pills
- Water pill to induce urination if needed

My Physician has explained that the following additional risks may be related to the treatment program that I am receiving: radiation exposure, kidney and/or liver damage, low blood counts, secondary cancer, hormonal crisis, and infertility.

I understand that during the course of this treatment, unforeseen conditions may arise which could require the planned treatment to be changed. All changes to the treatment plan will be discussed with me.

I received information and discussed with my Physician the possible alternative methods of treatment, the probability that the proposed treatment will be successful, and the probability of recovery if no treatment is received. No guarantee or assurance has been made to me as to the results that may be expected or that side effects or complications of treatment will not occur. I also understand that I may stop this treatment at any time.

I acknowledge that my Physician and I have discussed the information set forth above, that I have received information about my diagnosis, prognosis and treatment plan, that I have been given an opportunity to ask questions and that my questions have been answered to my satisfaction. By signing below, I confirm that this form has been fully explained to me, that I have read it or have had it read to me, that the blanks have been filled in, that I understand the contents. I make this request for treatment and grant the authority set forth above voluntarily, and assume responsibility for my decision.

Patient/Representative Signature: _____

Patient/Representative Printed Name: _____

Date Signed: _____ Time: _____

As the Physician, APN, or PA obtaining this consent, I have explained the anticipated benefits, relevant risks and alternatives with this patient and/or representative.

Signature of Person Obtaining Consent: _____

Printed Name of Person Obtaining Consent:
_____Pager # _____

Date Signed: _____ Time: _____

Signature of Attending Physician: _____

Printed Name of Attending Physician:
_____Pager # _____

Date Signed: _____ Time: _____

^{177}LU-DOTATATE APPENDIX 4: PATIENT EDUCATION

What is Lutathera used for?

• Lutathera is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors. This drug binds to somatostatin receptor expressing cells and is internalized. Upon internalization, Lutathera induces cell damage by formation of free radicals.

How is Lutathera given?

• Lutathera is administered via intravenous infusion over approximately 30 minutes every 8 weeks for a total of 4 doses. An intravenous amino acid solution is initiated 30 minutes prior to Lutathera and continued for 4 hours. You will also receive an injection of octreotide LAR the day after your Lutathera infusion.

What are the possible side effects of Lutathera?

The following side effects are common (>20%):

• Nausea/vomiting

• Abdominal pain/diarrhea

•Fatigue

• Swelling of the extremities

• Myelosuppression (low blood counts)

• Hyperglycemia (high blood sugar)

• Nephrotoxicity (kidney damage)

• Hyperuricemia (high uric acid)

• Hypocalcemia/kalemia (low calcium and potassium)

• Hepatotoxicity (liver damage)

These side effects are less common:

• Secondary cancers

• Neuroendocrine hormonal crises (tumor-hormone release)

• Back pain

• Headache/dizziness

• Alopecia

• It is important to note that adverse effects for Lutathera alone are not available as it has only been studied in combination with octreotide.

What should I discuss with my provider before taking Lutathera?

• Inform your doctor if you are or wish to become pregnant.

• Inform your doctor if you are incontinent (unable to control your urine or stool).

What self-care measures does Lutathera require?

• Keep your body fluids from coming in contact with family members or caregivers.

• After going to the bathroom, be sure to wash your hands thoroughly and flush the toilet several times.

• Promptly clean up spilled bodily waste, wearing gloves when you clean. Dispose of gloves as directed by the healthcare provider who gave you your Lutathera treatment. Wash your hands when you are finished.

• Wash soiled clothing right away and wash separately from other clothing.

• Drink at least two to three quarts of fluid every 24 hours, unless you are instructed otherwise.

• ou may be at risk of infection so try to avoid crowds or people with colds, and report fever or any other signs of infection immediately to your health care provider.

• Use an electric razor and a soft toothbrush to minimize risk of bleeding.

• To reduce nausea, take anti-nausea medications as prescribed by your doctor, and eat small, frequent meals.