The 1st and only SSA* that is FDA-approved to treat both: adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival... and adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

*SSA=somatostatin analog.

HOW TO ADMINISTER

SOMATULINE® DEPOT
(lanreotide) Injection 120 mg

Remember: This is a single-use syringe with a retractable needle. All the medication must be used during this injection. Follow these instructions carefully—this procedure may be different from your past experience. If you have any questions about this medication or procedure, or if the syringe is dropped or damaged in any way, call 1-855-463-5127. The full Instructions for Use for Somatuline® Depot are located in the box containing the syringe.

1 Bring medication to room temperature
Remove box containing syringe pouch from refrigerator, and take out contents. Let pouch sit for 30 minutes to reach room temperature. Do not open pouch until ready to inject; injecting cold medication may be painful for patient.

Check to ensure:
• Date of this injection is as prescribed
• Pouch containing syringe is sealed and undamaged

2 Get patient comfortable
Ask patient to either lie down or remain standing.
Tell patient it is important that they remain still during the injection.
Wash hands.

Follow physician’s or institution’s policy on use of medical exam gloves

3 Remove syringe from pouch
Starting at notch, tear open pouch along dotted line. Set syringe on empty pouch.

Double-check:
• Dose is 120 mg
• Expiration date has not passed
• Syringe contents are white to pale yellow in appearance
If you have any questions, call 1-855-463-5127.

IMPORTANT SAFETY INFORMATION

Contraindications
• SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

Warnings and Precautions
• Cholelithiasis and Gallbladder Sludge
  − SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
  − Periodic monitoring may be needed.

Please see full Important Safety Information on page 3; click here for the full Prescribing Information and Patient Information.
Identify and clean injection site

Decide which side of the buttocks you will inject (right or left).
- Alternate injection site, from right buttock to left buttock and vice versa, for each injection
- Avoid areas with moles, scar tissue, reddened skin, or skin that feels bumpy
- Clean the selected area

Only inject in the upper outer quadrants of the right or left buttocks

Prep syringe, injection site

- Holding device in 1 hand, twist off plunger protector and remove needle cap; discard both
- Hold device by needle guard
- Using other hand, stretch the skin at the area of administration to flatten the injection area
- Do not pinch skin

Insert needle

- Position needle perpendicular to skin (90° angle)
- Using a strong, straight, dart-like motion, insert needle all the way into skin; no part of needle should be visible once fully inserted
- Do not aspirate (do not draw back)

Deep subcutaneous administration requires 90° angle of injection

Release hand, inject drug

- When needle is completely inserted, you may release skin that had been stretched. Push plunger with steady, firm pressure
  - Note: Pushing plunger too fast may cause discomfort to the patient or may break the device
- While depressing plunger, count to 20 seconds and continue steady pressure on plunger; give plunger a final push to engage needle. Confirm plunger is at the bottom and no medication remains

Remove needle

- While continuing to hold down plunger, remove needle from patient’s skin
- Allow needle to retract by removing thumb from plunger
- If needed, gently apply gauze pad to injection area
- Discard syringe following your institution’s disposal policies, and wash hands

Never rub or massage the injection site
INDICATIONS
SOMATULINE® DEPOT (lanreotide) Injection is a somatostatin analog indicated for:

• the treatment of adult patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival; and
• the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

IMPORTANT SAFETY INFORMATION
Contraindications
• SOMATULINE DEPOT is contraindicated in patients with hypersensitivity to lanreotide. Allergic reactions (including angioedema and anaphylaxis) have been reported following administration of lanreotide.

Warnings and Precautions
• Cholelithiasis and Gallbladder Sludge
  – SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
  – Periodic monitoring may be needed.

• Hypoglycemia or Hyperglycemia
  – Pharmacological studies show that SOMATULINE DEPOT, like somatostatin and other somatostatin analogs, inhibits the secretion of insulin and glucagon. Patients treated with SOMATULINE DEPOT may experience hypoglycemia or hyperglycemia.
  – Blood glucose levels should be monitored when SOMATULINE DEPOT treatment is initiated, or when the dose is altered, and antidiabetic treatment should be adjusted accordingly.

• Cardiovascular Abnormalities
  – SOMATULINE DEPOT may decrease heart rate.
  – In patients in the GEP-NET pivotal trial, 23% of SOMATULINE DEPOT-treated patients had a heart rate of less than 60 bpm compared to 16% of placebo-treated patients. The incidence of bradycardia was similar in the treatment groups. Initiate appropriate medical management in patients with symptomatic bradycardia.
  – In patients without underlying cardiac disease, SOMATULINE DEPOT may lead to a decrease in heart rate without necessarily reaching the threshold of bradycardia. In patients suffering from cardiac disorders prior to treatment, sinus bradycardia may occur. Care should be taken when initiating treatment in patients with bradycardia.

Most Common Adverse Reactions
• GEP-NETs: Adverse reactions occurring in greater than 10% of patients who received SOMATULINE DEPOT in the GEP-NET trial were abdominal pain (34%), musculoskeletal pain (19%), vomiting (19%), headache (16%), injection site reaction (15%), hyperglycemia (14%), hypertension (14%), and cholelithiasis (14%).

• Carcinoid Syndrome: Adverse reactions occurring in the carcinoid syndrome trial were generally similar to those in the GEP-NET trial. Adverse reactions occurring in greater than 5% of patients who received SOMATULINE DEPOT in the carcinoid syndrome trial and occurring at least 5% greater than placebo were headache (12%), dizziness (7%) and muscle spasm (5%).

Drug Interactions: SOMATULINE DEPOT may decrease the absorption of cyclosporine (dosage adjustment may be needed); increase the absorption of bromocriptine; and require dosage adjustment for bradycardia-inducing drugs (e.g., beta-blockers).

Special Populations
• Lactation: Advise women not to breastfeed during treatment and for 6 months after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for the full Prescribing Information and Patient Information.