

HOW TO ADMINISTER



Somatuline® Depot is a somatostatin analog (SSA) indicated to improve progression-free survival (PFS) in gastroenteropancreatic neuroendocrine tumors (GEP-NETs) and proven to reduce the need for rescue medication in carcinoid syndrome in appropriate patients.^{1,2}

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



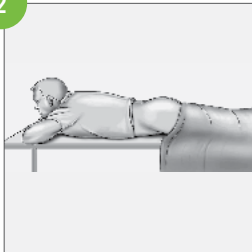
Bring medication to room temperature

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:

- Dose 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 with soap and water.

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 the prefilled syringe on a clean surface.

Double-check:

- Dose is 120 mg and the expiration has not passed
- Inspect the syringe visually: DO NOT administer if particulate matter or discoloration is observed

NOTE: content is a semi-solid phase having a gel-like appearance, with viscous characteristics and a color varying from white to pale yellow. It can contain micro bubbles that can clear up during injection. These differences are normal and do not interfere with the quality of the product.

Administration steps continued on page 2

IMPORTANT SAFETY INFORMATION

Contraindications

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

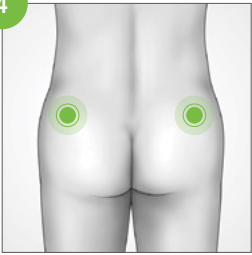
Warnings and Precautions

- **Cholelithiasis and Gallbladder Sludge**
 - SOMATULINE DEPOT may reduce gallbladder motility and lead to gallstone formation.
 - Periodic monitoring may be needed.
 - If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.

Please see Indications and full Important Safety Information on page 3; click here for the full [Prescribing Information](#) and [Patient Information](#).



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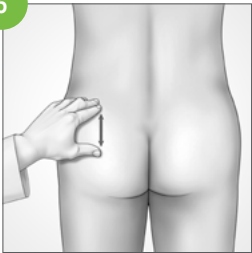
Identify and clean injection site

Decide which side of the buttocks to 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

5

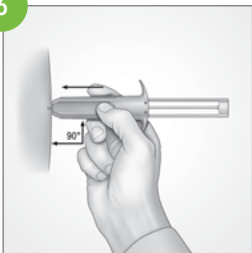


Prep syringe, injection site

ALL the medication must be injected during this use.

- Remove the prefilled syringe from its tray, and remove needle cap; discard both
- Hold prefilled syringe by the syringe body, **DO NOT HOLD** it by the plunger
- Using other hand, stretch the skin at the area of administration to **FLATTEN** the injection area
- Do **NOT** pinch skin

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Insert needle

- Position needle **perpendicular** to skin (90° angle)
- Using a strong, straight, dart-like motion, insert needle **all the way into** skin
- It is very important that you insert the needle **COMPLETELY**. You should not see any needle once it is fully inserted
- Do not aspirate (do not draw back)

Deep subcutaneous administration requires 90° angle of injection

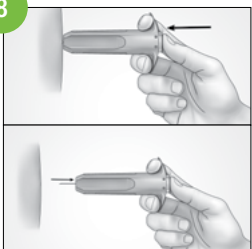
7



Release hand, inject drug

- When needle is completely inserted, you may release skin that had been stretched. Push plunger with **steady, firm pressure** with your thumb
 - Note: The medication is thicker and harder to push than you might expect. Pushing plunger too fast may cause discomfort to the patient
- 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

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Remove needle

- While **continuing to hold down plunger**, remove needle from patient's skin
- Allow needle to retract by removing thumb from plunger
 - Note: If needle does not retract, push plunger again to engage safety mechanism. The needle will then retract
- If needed, gently apply gauze pad to injection area
- Dispose of Pre-filled Syringe. Discard used device into a hard plastic container with a screw top (such as a detergent bottle) or sharps container as per your institutional policy. Wash hands

Never rub or massage the injection site

INDICATIONS

SOMATULINE® DEPOT (lanreotide) 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.
- If complications of cholelithiasis are suspected, discontinue SOMATULINE DEPOT and treat appropriately.

• Hypoglycemia or Hyperglycemia

- 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 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.

• Steatorrhea and Malabsorption of Dietary Fats

- New onset steatorrhea, stool discoloration and loose stools have been reported in patients receiving somatostatin analogs, including SOMATULINE DEPOT. Somatostatin analogs reversibly inhibit secretion of pancreatic enzymes and bile acids, which may result in malabsorption of dietary fats and subsequent symptoms of steatorrhea, loose stools, abdominal bloating, and weight loss.
- If new occurrence or worsening of these symptoms are reported in patients receiving SOMATULINE DEPOT, evaluate patients for potential pancreatic exocrine insufficiency and manage accordingly.

Most Common Adverse Reactions

- **GEP-NETs:** Adverse reactions in >10% of patients who received SOMATULINE DEPOT 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 in ≥5% of patients who received SOMATULINE DEPOT and 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**.