Sandostatin® LAR Depot (octreotide acetate) for injectable suspension

MIXING & ADMINISTRATION GUIDE[1,2]

Injection should be administered by a health care professional. Successful preparation and administration of Sandostatin LAR Depot relies on properly adhering to the steps below. Not following these steps can result in failure to appropriately deliver the drug.

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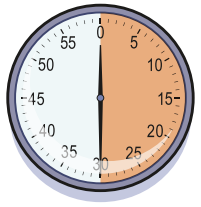

Step 1

- Remove from refrigerated storage*
- **Only start the reconstitution process after the injection kit has reached room temperature**
- **Let the kit stand at room temperature for a minimum of 30 minutes before reconstitution, but do not exceed 24 hours**
- The injection kit can be rerefrigerated if needed

Step 2

- Remove plastic cap from vial and clean rubber stopper of vial with an alcohol wipe

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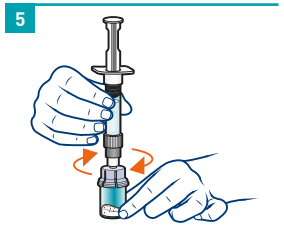

Step 3

- Remove lid film of vial adapter packaging; **do not** remove vial adapter from its packaging
- Place the vial on a flat surface. Holding the vial adapter packaging, position the vial adapter on top of the vial and push it fully down so it snaps into place, confirmed by an audible "click"
- Lift packaging off vial adapter with a vertical movement

Step 4

- Peel off outer syringe label and inspect syringe, ensuring there are no visible particles

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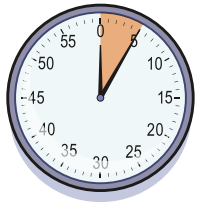

Step 5

- Remove cap from syringe and screw syringe onto vial adapter
- Slowly push plunger all the way down, transferring all diluent solution in the vial

Step 6

- **Let vial stand for a minimum of 2 minutes and up to 5 minutes** to ensure that the diluent has fully saturated the powder
- It is normal that the plunger rod may move up if there is overpressure in the vial
- **At this stage prepare patient for injection**

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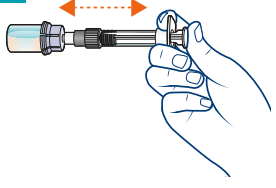


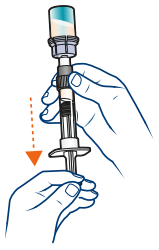
Step 7

- After saturation period, ensure plunger is pushed all the way down in the syringe
- Keep plunger pressed and **shake vial moderately in a horizontal direction for a minimum of 30 seconds** so the powder is completely suspended (milky uniform suspension). **If it is not completely suspended, repeat moderate shaking for another 30 seconds**

*For prolonged storage, Sandostatin LAR Depot should be stored at refrigerated temperatures between 2°C to 8°C (36°F to 46°F) and protected from light until the time of use.

For full mixing and administration instructions, see the Instruction Booklet.

8



Step 8

- Turn syringe and vial upside down, slowly pull plunger back, and draw contents from vial into syringe
- Unscrew syringe from vial adapter

Step 9

- Prepare injection site with an alcohol wipe
- Screw safety injection needle onto syringe
- Gently **reshake** syringe to a milky uniform suspension
- Pull protective cover off needle and gently tap syringe to remove and expel any visible bubbles
- **Proceed immediately** to Step 10 for administration to the patient; **any delay may result in sedimentation**

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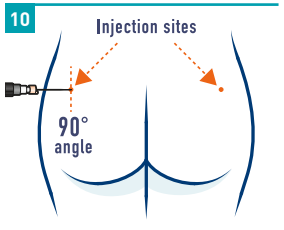

Step 10

- Sandostatin LAR Depot must be given only by deep intragluteal injection, **NEVER** intravenously
- Insert needle fully into left or right gluteus at a 90° angle to the skin
- Slowly pull back plunger to check that no blood vessel has been penetrated (if so, reposition)
- **Depress plunger with steady pressure** until syringe is empty and withdraw needle

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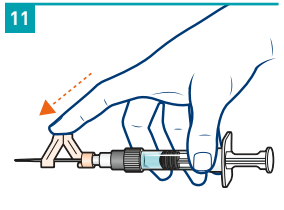

Step 11

- Activate safety guard over the needle by either:
  – pressing hinged section of safety guard down onto a hard surface, or
  – pushing hinge forward with your finger
- An audible "click" confirms proper activation
- Record injection site on patient's record; **alternate monthly**

Step 12

- Immediately dispose of syringe in a sharps container
- **Special precautions for disposal:** Any unused product or waste material should be disposed of in accordance with local requirements

Pain on injection, which is generally mild to moderate and short-lived (usually about 1 hour), is dose related. In carcinoid patients where a diary was kept, pain at the injection site was reported by about 20% to 25% at the 10-mg dose and by about 30% to 50% at the 20- and 30-mg doses.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Treatment with Sandostatin LAR Depot may affect gallbladder function, with postmarketing reports of cholelithiasis (gallstones) resulting in complications; glucose metabolism; thyroid and cardiac function; and nutritional absorption (periodic monitoring is recommended). Cardiac function: use with caution in at-risk patients.

Please see additional Important Safety Information on the next page.
Please click here for full Prescribing Information.

Sandostatin® LAR Depot
(octreotide acetate) for injectable suspension
10mg • 20mg • 30mg

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

Pain at the Injection Site

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INDICATIONS AND USAGE

Sandostatin® LAR Depot (octreotide acetate) for injectable suspension is indicated for patients in whom initial treatment with immediate-release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated for

- Long-term maintenance therapy in patients with acromegaly who have had inadequate response to surgery and/or radiotherapy or for whom surgery and/or radiotherapy is not an option (the goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal)
- Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- Long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors

In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and Sandostatin LAR Depot on tumor size, rate of growth, and development of metastases has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Gallbladder abnormalities may occur. There have been postmarketing reports of cholelithiasis (gallstones) resulting in complications, including cholecystitis, cholangitis, pancreatitis, and requiring cholecystectomy in patients taking Sandostatin LAR Depot. Patients should be monitored periodically. If complications of cholelithiasis are suspected, discontinue Sandostatin LAR Depot and treat appropriately
- Glucose Metabolism: Hypoglycemia or hyperglycemia may occur. Blood glucose levels should be monitored when Sandostatin LAR Depot treatment is initiated or when the dose is altered. Anti-diabetic treatment should be adjusted accordingly
- Thyroid Function: Hypothyroidism may occur. Baseline and periodic assessment of thyroid function (TSH, total and/or free T4) is recommended
- Cardiac Function: Bradycardia, arrhythmia, conduction abnormalities, and other electrocardiogram changes may occur. The relationship of these events to octreotide acetate is not established because many of these patients have underlying cardiac disease. Use with caution in at-risk patients
- Nutrition: Octreotide may alter absorption of dietary fats. Monitoring of vitamin B_{12} levels is recommended during therapy with Sandostatin LAR Depot. Patients on total parenteral nutrition and octreotide should have periodic monitoring of zinc levels

Drug Interactions

- The following drugs require monitoring and possible dose adjustment when used with Sandostatin LAR Depot: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine. Octreotide has been associated with alterations in nutrient absorption, so it may have an effect on absorption of orally administered drugs. Drugs mainly metabolized by CYP3A4 and which have a low therapeutic index should be used with caution
- Octreotide competitively binds to somatostatin receptors and may interfere with the efficacy of lutetium Lu 177 dotatate. Discontinue Sandostatin LAR Depot at least 4 weeks prior to each lutetium Lu 177 dotatate dose

Adverse Reactions

The most common adverse reactions occurring in patients receiving Sandostatin LAR Depot are

- Acromegaly: biliary abnormalities (52%), diarrhea (36%-48%), cholelithiasis (13%-38%), abdominal pain or discomfort (11%-29%), flatulence (26%), influenza-like symptoms (20%), constipation (19%), headache (15%), anemia (15%), hyperglycemia (15%), injection-site pain (2%-14%), hypertension (13%), dizziness (12%), fatigue (11%), nausea (10%), vomiting (7%), hypothyroidism (2%), hypoglycemia (2%), and goiter (2%)
- Carcinoid Tumors and VIPomas: biliary abnormalities (62%), injection-site pain (20%-50%), nausea (24%-41%), abdominal pain (10%-35%), fatigue (8%-32%), headache (16%-30%), hyperglycemia (27%), back pain (8%-27%), constipation or vomiting (15%-21%), dizziness (18%-20%), sinus bradycardia (19%), pruritus (18%), upper respiratory tract infection (10%-18%), myalgia (4%-18%), flatulence (9%-16%), arthropathy (8%-15%), rash (15%), generalized pain (4%-15%), sinusitis (5%-12%), conduction abnormalities (9%), hypoglycemia (4%), and arrhythmia (3%)

Please click here for full Prescribing Information.

References: 1. Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2021. **2.** *Instruction Booklet: Preparation and Administration of Sandostatin LAR Depot (octreotide acetate for injectable suspension).* East Hanover, NJ: Novartis Pharmaceuticals Corp; 2016.

Learn more about the mixing and administration of Sandostatin LAR Depot at **Sandostatin-administration.com**

If you still have questions about the preparation and/or administration of Sandostatin LAR Depot, please call **1-888-NOW-NOVA (1-888-669-6682)**.

Contact a Clinical Educator (CE) for an in-office mixing and administration demonstration at **Sandostatin-nurse.com**.

NOVARTIS

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10mg • 20mg • 30mg

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