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

ADDITIONAL CONSIDERATIONS FOR DORSOGLUTEAL AND VENTROGLUTEAL INTRAMUSCULAR INJECTIONS

A closer look at step 10 of the mixing and administration process for Sandostatin® LAR Depot (octreotide acetate) for injectable suspension.
See page 5 for complete instructions for use.

INDICATIONS AND USAGE

Sandostatin® LAR Depot (octreotide acetate) for injectable suspension is indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors and long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors in patients in whom initial treatment with immediate-release Sandostatin® (octreotide acetate) Injection has been shown to be effective and tolerated. 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.

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 page 6.
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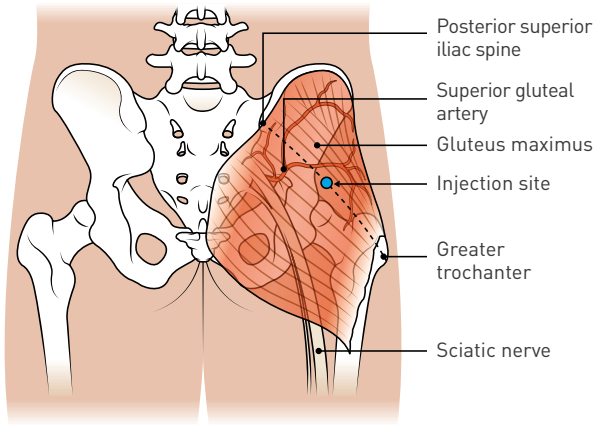
DORSOGLUTEAL INTRAMUSCULAR (IM) INJECTIONS

Dorsogluteal injections are given in the outer upper quadrant of the gluteus maximus muscle[1-3]



FIRST | Maximize patient comfort by properly positioning the patient before palpating[4]

- Instruct the patient to remove all clothing from the injection site so that it may be fully visualized and bony landmarks palpated[4]
- Instruct the patient to lie in a fully prone position with the toes pointed inward to relax the gluteal muscles[4]
- Palpate for the greater trochanter (GT)—the knobby top portion of the femur (about the size of a golf ball)[5]
- Palpate the posterior superior iliac spine (PSIS)—many people have dimples over this bone[5]

NEXT | Find the injection site[5]

- Draw an imaginary line between the GT (the golf ball-sized knobby top portion of the femur) and the PSIS[5]
- After locating the center of the imaginary line, find a point 2 cm above. This is your injection site[1,5]

THEN | Inject into the site[2,4,6]

- In patients with greater adipose tissue to muscle depth, stretch skin tight between two fingers and hold[2]
- For patients who are thinner and with little adipose tissue, pull the muscle and skin up or "bunch" the skin 2 cm to 3 cm from the injection site with your nondominant hand[2,6]
- While holding the syringe like a pencil or dart, insert the needle at a 90° angle[2]
- Inject the medication with steady pressure[7]

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION (Continued)

Drug Interactions:

- The following drugs require monitoring and possible dose adjustment when used with Sandostatin® LAR Depot (octreotide acetate) for injectable suspension: cyclosporine, insulin, oral hypoglycemic agents, beta-blockers, and bromocriptine
- For lutetium Lu 177 dotatate injection: Discontinue Sandostatin LAR Depot at least 4 weeks prior to each lutetium Lu 177 dotatate dose

See page 5 for full instructions for use on administering Sandostatin LAR Depot.

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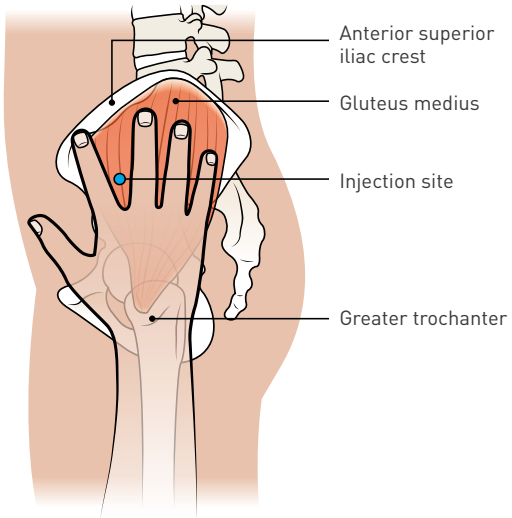
VENTROGLUTEAL INTRAMUSCULAR (IM) INJECTIONS

Ventrogluteal injections are given in the gluteus medius muscle, which is located on top of the gluteus minimus muscle[3]



FIRST | Maximize patient comfort by properly positioning the patient before palpating[4]

- Instruct the patient to remove all clothing from the injection site so that it may be fully visualized and bony landmarks palpated[4]
- Decide whether the patient will stand, sit, or lie in a supine or lateral position. Having the patient lay down helps the clinician visualize the site correctly[4]
- Position the patient to relax the gluteal muscles; internal rotation of the femur relaxes them[4]
- Palpate for the greater trochanter (GT)—the knobby top portion of the femur (about the size of a golf ball)[5]
- Palpate the anterior/lateral Iliac crest (the superior border of the iliac bone)[5,8]

NEXT | Find the injection site[5]

- Place the palm of your hand over the GT. Point the first (index) finger toward the anterior iliac crest. Spread the second (middle) finger toward the back, making a "V." The thumb should always be pointed toward the front of the leg. Always use the index and middle fingers to make the "V." The injection will be given between the knuckles of your index and middle fingers[5]

THEN | Inject into the site[2,4,6]

- In patients with greater adipose tissue to muscle depth, stretch skin tight between two fingers and hold[2]
- For patients who are thinner and with little adipose tissue, pull the muscle and skin up or "bunch" the skin 2 cm to 3 cm from the injection site with your nondominant hand[2,6]
- While holding the syringe like a pencil or dart, insert the needle at a 90° angle[2]
- Inject the medication with steady pressure[7]

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION (Continued)

Adverse Reactions:

• The most common adverse reactions occurring in ≥20% of patients are back pain, fatigue, headache, abdominal pain, nausea, and dizziness.

See page 5 for full instructions for use on administering Sandostatin® LAR Depot (octreotide acetate) for injectable suspension.

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IM INJECTION REMINDERS

- IM injection techniques include using the right angle of injection, adjusting for thickness of adipose tissue, and finding the correct injection site[1,4]
- Clean the site with an alcohol swab[2,6]
- Apply gentle pressure to the injection site with a gauze swab[6]
- Record the injection site on the patient's chart[2]
- Injection sites should be rotated in a systematic manner to avoid irritation[9]
- Deltoid injections should be avoided due to significant discomfort at the injection site when given in that area[9]

Health care professionals should use their professional judgment in selecting the proper site for IM injections.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Treatment with Sandostatin® LAR Depot (octreotide acetate) for injectable suspension 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.

References: 1. Boyd AE, DeFord LL, Mares JE, et al. Improving the success rate of gluteal intramuscular injections. *Pancreas*. 2013;42(5):878-882. **2.** Hunter J. Intramuscular injection techniques. *Nurs Stand*. 2008;22(24):35-40. **3.** Greenway K. Using the ventrogluteal site for intramuscular injection. *Nurs Stand*. 2004;18(25):39-42. **4.** Nicoll LH, Hesby A. Intramuscular injection: an integrative research review and guideline for evidence-based practice. *Appl Nurs Res*. 2002;16(2):149-162. **5.** Cocoman A, Murray J. IM injections: how's your technique? *Clin Pract WIN*. 2006:50-51. https://www.inmo.ie/MagazineArticle/PrintArticle/5676. Accessed August 19, 2019. **6.** Workman B. Safe injection techniques. *Nurs Stand*. 1999;13(39):47-53. **7.** *Instruction Booklet: Preparation and Administration of Sandostatin LAR Depot (octreotide acetate) for injectable suspension*. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2019. **8.** Cocoman A, Murray J. Intramuscular injections: a review of best practice for mental health nurses. *J Psychiatr Ment Health Nurs*. 2008;15(5):424-434. **9.** Sandostatin LAR Depot [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2021.

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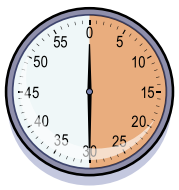
Sandostatin® LAR Depot (octreotide acetate) for injectable suspension

MIXING & ADMINISTRATION GUIDE[1,2]

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

1



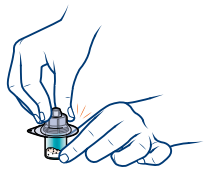
Step 1

- 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

3



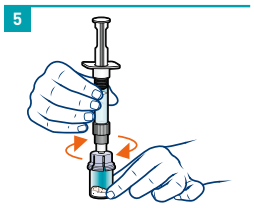
Step 3

- 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

5



Step 5

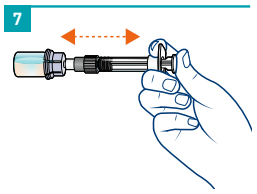
- Remove cap from syringe and screw syringe onto vial adapter
- Slowly push plunger all the way down, transferring all diluent solution in the vial

6

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**

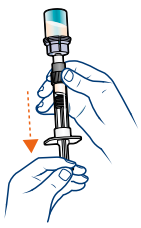
7



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**

8



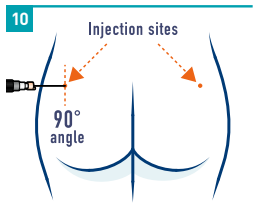
Step 8

- 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**

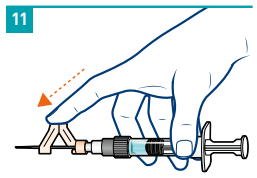
10



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

11



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**

12

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.

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

*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.

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; 2019.

HIGHLIGHTS OF IMPORTANT SAFETY INFORMATION (Continued)

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
- For lutetium Lu 177 dotatate injection: 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 ≥20% of patients are back pain, fatigue, headache, abdominal pain, nausea, and dizziness.

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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 (octreotide acetate) for injectable suspension. 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 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%)

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NOVARTIS

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