Product Fact Sheet

Supplied and Marketed by	IPSEN BIOPHARMACEUTICALS, INC. Phone: 1-866-837-2422 Internet: www.IpsenUS.com www.SomatulineDepot.com
Product Name	Somatuline® Depot
Established Name	Lanreotide
Indications	SOMATULINE® DEPOT (lanreotide) Injection is a somatostatin analog indicated for: • the long-term treatment of patients with acromegaly who have had an 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 growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal; • 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.

Product Information

NDC	Description	Dispensing/Sale Pack Quantity
15054-1060-03	60 mg/0.2 mL sterile, prefilled syringe	1
15054-1090-03	90 mg/0.3 mL sterile, prefilled syringe	1
15054-1120-03	120 mg/0.5 mL sterile, prefilled syringe	1

Product Availability	Somatuline® Depot continues to be available through your wholesaler as a Specialty Distributor sourced product or directly through a number of Specialty Distributors. Please contact your supplier for a list of Specialty Distributors. A limited number of Specialty Pharmacies are also authorized to dispense the medication; please call IPSEN CARES® at 866-435-5677 to assess if a patient's insurance allows this medication to be accessed through Specialty Pharmacy.
Dispensing Pack Dimensions	**Somatuline® Depot** Approximate dimensions – unit Depth: 3.5", height: 0.8", width: 12"
Storage and Handling Information	Store SOMATULINE® DEPOT in the refrigerator at 2°C to 8°C (36°F to 46°F). Protect from light. Store in the original package.
Sales Unit to Trade	One dispensing pack.
Product Expiration	The expiration date is printed on each dispensing pack and syringe label.
Prescription Legend	Prescription only.
Dosage and Administration	**Administration** • For deep subcutaneous injection only • Intended for administration by a healthcare provider • Administer in the superior external quadrant of the buttock • Alternate injection sites **Recommended Dosage** • Acromegaly: 90 mg every 4 weeks for 3 months. Adjust thereafter based on GH and/or IGF-1 levels. See full Prescribing Information for titration regimen • GEP-NETs: 120 mg every 4 weeks • Carcinoid syndrome: 120 mg every 4 weeks. If patients are already being treated with SOMATULINE® DEPOT for GEP-NETs, do not administer an additional dose for carcinoid syndrome
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. **Please see additional Important Safety Information throughout.**

Please see accompanying full Prescribing Information and Patient Information.

Somatuline® Depot (lanreotide) Injection

Product Fact Sheet

Important Safety Information (Continued)

- **Cardiovascular Abnormalities:**
  - SOMATULINE DEPOT may decrease heart rate.
  - In cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.
  - 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.
- **Thyroid Function Abnormalities**
  - Slight decreases in thyroid function have been seen during treatment with lanreotide in acromegalic patients.
  - Thyroid function tests are recommended where clinically appropriate.
- **Monitoring/Laboratory Tests:** In acromegaly, serum GH and IGF-1 levels are useful markers of the disease and effectiveness of treatment.

Please see additional Important Safety Information throughout.

Special Shipping Requirements

Somatuline® Depot is labeled with specific transportation and storage requirements. Care should be taken to ensure that temperature control at 2°C to 8°C (36°F to 46°F) is maintained during these activities. When shipping Somatuline® Depot, a foam or gel refrigerant ice that has been frozen hard at -18°C (0°F) for a minimum of 24 hours should be used. Somatuline® Depot should never be exposed to dry ice. Ipsen will ship Somatuline® Depot in a manner that maintains its temperature to meet the requirements stated above during transport from Ipsen to the product destination. Specialty Distributors and Specialty Pharmacies should also package and ship Somatuline® Depot in a manner that maintains this same environment.

Customers should call 1-855-463-5127 if they have any questions pertaining to proper shipping.

Product Returns

Credit for returns is subject to Ipsen's current Return Goods Policy. Please contact Returns.USA@Ipsen.com for more information or to receive a Return Goods Authorization

Order Information

Ipsen Customer Service: 1-844-944-7736

Product Information

Ipsen Medical Affairs
Phone: 1-855-463-5127
Fax: 1-866-681-1063
Email: medinfo.USA@ipsen.com

Reimbursement Information

IPSEN CARES® 1-866-435-5677
Monday through Friday 8:00 AM to 8:00 PM ET

Patient Support Program

IPSEN CARES® provides coverage, access, reimbursement, and educational support to patients and their healthcare professionals.

IPSEN CARES®: 1-866-435-5677
Monday through Friday 8:00 AM to 8:00 PM ET

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Important Safety Information (Continued)

Adverse Reactions

- **Acromegaly:** Adverse reactions occurring in greater than or equal to 9% of patients who received SOMATULINE DEPOT in the overall pooled safety studies in acromegaly were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), and injection-site reactions (9%).
- **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.
- **Moderate to Severe Renal and Hepatic Impairment:** See full prescribing information for dosage adjustment in patients with acromegaly.

Please see accompanying full Prescribing Information and Patient Information.

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