

IPSEN CARES[®]

Coverage, Access, Reimbursement & Education Support

The Nurse Home Health Administration Program

**Making
Somatuline[®] Depot
(lanreotide) Injection
treatment more
accessible for your
eligible* patients**

*Patient eligibility restrictions
available on page 3.



Actor portrayal

INDICATIONS

SOMATULINE[®] DEPOT (lanreotide) 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.

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information and Patient Information.



Somatuline[®] Depot
(lanreotide) Injection 60mg, 90mg and 120mg



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The Nurse Home Health Administration Program

Our nurses can help keep your eligible patients connected to treatment

Intended for administration by a healthcare provider

As a healthcare provider who recognizes the benefits Somatuline[®] Depot (lanreotide) Injection can offer your patients, you understand the importance of proper administration of every injection. But you also know that visits to the office for injections are often difficult.

Created for patients who find it difficult to make it to the office regularly, the Nurse Home Health Administration Program helps ensure your eligible patients receive Somatuline Depot treatment from a registered nurse without having to leave their homes or their workplaces.

The program is not intended to replace regular office visits or the care you are providing your patients. To keep you up-to-date, you will be sent regular reports to confirm that your patients receive Somatuline Depot as you have prescribed.

Enrolling your eligible patients

Getting your patients started with the program is simple:

1. As the prescriber, you evaluate each of your patients and decide who may be appropriate to receive injections at home or at work.
2. Complete a Somatuline Depot IPSEN CARES[®] Enrollment Form and check the box indicating that the Nurse Home Health Administration Program is requested. You can download the form or enroll your patient online at www.ipsencares.com.
3. IPSEN CARES verifies the patient's benefits and program eligibility described on next page.

IMPORTANT SAFETY INFORMATION (continued)

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

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Coordinating Nurse At-Home/At-Work Administration

IPSEN CARES® coordinates the details of the Nurse Home Health Administration Program, including:

- **Shipments of Somatuline® Depot**
 - Once a patient's benefits are verified, an IPSEN CARES Patient Access Specialist manages the shipment of Somatuline Depot via Specialty Pharmacy.
 - Specialty Pharmacy then sends Somatuline Depot directly to the patient.
- **Assignment of a Home Health Nurse (HHN)**
 - Each patient is assigned an HHN who contacts the patient, confirms the date of the first injection, and schedules subsequent injections with the patient.
- **Notifications of administration**
 - After each visit, the HHN sends a fax to your office to confirm administration of the product to the patient.

Determining your patients' eligibility

The Nurse Home Health Administration Program is an additional offering of IPSEN CARES available at your direction for all eligible patients prescribed Somatuline Depot.

- A physician must prescribe Somatuline Depot to be administered by Nurse Home Health Administration for the patient.
- The program is available to most patients covered by commercial insurance plans.
- Patients may not participate if prescriptions are eligible to be paid in part or full by any state or federally funded programs, including, but not limited to Medicare or Medicaid, VA, DOD, or TRICARE.
- Residents of Massachusetts, Michigan, Minnesota, and Rhode Island are not eligible.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **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 cardiac studies with acromegalic patients, the most common cardiac adverse reactions were sinus bradycardia, bradycardia, and hypertension.
 - 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.

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For more information, visit www.ipsencares.com
or call (866) 435-5677 between 8:00 am and
8:00 pm ET, Monday through Friday.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued)

- **Thyroid Function Abnormalities**
 - Slight decreases in thyroid function have been seen during treatment with lanreotide in acromegaly 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.

Adverse Reactions

- **Acromegaly:** Adverse reactions in >5% of patients who received SOMATULINE DEPOT were diarrhea (37%), cholelithiasis (20%), abdominal pain (19%), nausea (11%), injection-site reactions (9%), constipation (8%), flatulence (7%), vomiting (7%), arthralgia (7%), headache (7%), and loose stools (6%).
- **GEP-NETS:** Adverse reactions >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 occurring 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.
- **Moderate to Severe Renal and Hepatic Impairment:** See full prescribing information for dosage adjustment in patients with acromegaly.

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 see accompanying full [Prescribing Information](#) and [Patient Information](#).