



Patient Assistance
Program Application

Fax Completed Form To:
1-888-525-2416

The Somatuline® Depot Patient Assistance Program (PAP) is designed to provide Somatuline® Depot at no cost to eligible patients. Patients may be eligible to receive free drug if they are experiencing financial hardship, have no insurance coverage, and received a prescription for an on-label use of Somatuline® Depot, as supported by information provided in the Program application. Eligibility does not guarantee approval for participation in the program. The Somatuline® Depot PAP provides Somatuline® Depot (lanreotide injection) product only, and does not cover the cost of previously purchased product or medical services.

Instructions: Both the patient and the healthcare provider have to complete the application.

PATIENT REQUIREMENTS

- Complete and sign the Patient Information section, including the Financial Information section.
- If you are seeking financial assistance from the PAP, please fax a copy of proof of total household income. Accepted forms include most recently filed Federal Tax Forms (i.e., Form 1040) including supporting documents (W-2), social security income (SSA 1099), or the completed Income Statement form included at the end of this application.

HEALTHCARE PROVIDER REQUIREMENTS

- Complete and sign the Healthcare Provider Information section.
- Verify that the patient is being prescribed and administered Somatuline® Depot.
- Ensure the entire application is complete and signed before sending it to the fax number provided above.

It is important that you and your healthcare provider complete all requested information and sign where indicated. Since incomplete or incorrect applications will delay the application process, please ensure all information provided is correct.

We recommend that you fax the completed form in order to expedite the process. Once the application is received, we will evaluate the patient's eligibility to participate in the Somatuline® Depot PAP. Healthcare providers will be notified upon completion of eligibility review. Please note that program rules are subject to change without notice. For further assistance, please call 1-866-435-5677 from 8:00 AM to 8:00 PM Eastern Time, Monday through Friday.

Please see Somatuline® Depot Important Safety Information on the following pages and accompanying [Patient Information](#) and full [Prescribing Information](#).

Sincerely,

The IPSEN Coverage, Access, Reimbursement & Education Support (CARES) program



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PATIENT INFORMATION: THIS SECTION TO BE COMPLETED BY THE PATIENT

First Name _____ MI _____ Last Name _____
 Date of birth (MM/DD/YYYY) ____/____/_____
 Mailing Address _____ Apt # _____
 City _____ State _____ Zip _____
 Social Security Number _____ Gender Male Female
 Daytime Phone Number (____) _____ Evening Phone Number (____) _____
 Email Address _____ Are you a US resident? Yes No
 Prescribing Physician _____ Treating Facility _____

PROOF OF ANNUAL HOUSEHOLD INCOME (REQUIRED)

My estimated annual household income currently is \$ _____
 (Please include dollar amount of monthly income from)
 \$ _____ Social Security Disability Income (SSDI) (beginning ____/____/____)
 \$ _____ Supplemental Security Income (SSI)
 \$ _____ Aid from the Department of Public Welfare
 \$ _____ Unemployment Benefits (from ____/____/____ to ____/____/____)
 \$ _____ Workers Compensation Benefits (from ____/____/____ to ____/____/____)
 \$ _____ Dividends, interest, or investment accounts
 \$ _____ Employment (myself and/or my spouse)
 \$ _____ Other (includes assistance from family, friends, charity, or church. Please specify the amount of financial assistance you receive - may include percentage of rent, food, etc.)
 Number of People in Household _____

Insurance Type	Status	Status	Please indicate Primary (P) or Secondary (S)
Commercial	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
Medicaid	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
Medicare	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
TriCare	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
Healthcare Exchange	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
Other	<input type="checkbox"/> Approved <input type="checkbox"/> Denied <input type="checkbox"/> Waiting for Decision	____/____/____	
<input type="checkbox"/> Uninsured	Patient is not eligible for any public health insurance, which includes Medicare and Medicaid, or has been denied coverage by a third-party payer.		

I authorize my doctor(s) and their staff to disclose my personal information, including information about my insurance, prescription, medical condition, and health ("PHI") to Ipsen Biopharmaceuticals, Inc. and/or its agents or third party vendors ("Ipsen") and the Somatuline® Depot Patient Assistance Program (the "PAP"). I know that the information I provide will be used by the PAP to: (1) decide if I am eligible for assistance; (2) operate the PAP; (3) send me information about the PAP and other programs that might help me pay for my medicines; (4) send my information to other programs that might help me pay for my medicines; (5) ask me for financial, insurance, and/or medical information; and/or (6) share my information as required or permitted by law. I authorize the PAP to use information on this Application and any other information I give to the PAP for these same reasons. I also give Ipsen permission to share my PHI and other information with people and companies that work with the PAP; government agencies, including the Centers for Medicare and Medicaid Services; insurance companies, including Medicare Part D plans; my doctor(s) and other people, or institutions who are involved in my healthcare, such as pharmacies and hospitals; and/or other organizations that might help me pay for my medication. I promise that any information, including financial and insurance information, that I provide to the PAP is complete and true, and unless I have said something different in this application, I have no insurance coverage for this product, which includes Medicaid, Medicare, or any public or private assistance programs or any other form of insurance. If my income or health insurance coverage changes, I will notify IPSEN CARES® at 1-866-435-5677. I understand that Ipsen has the right to contact me directly to confirm receipt of medications. Ipsen may revise, change, or terminate this program at any time. All information that I provide may be used by Ipsen, or any third party working on behalf of Ipsen, in connection with the PAP. I understand that once my PHI has been disclosed to Ipsen, it is no longer protected by federal privacy laws and Ipsen may re-disclose it; however, Ipsen has agreed to protect my PHI by using and disclosing it only for the purposes described above or as required by law. I can withdraw this authorization by contacting IPSEN CARES® at 1-866-435-5677 or mailing a letter requesting such revocation to IPSEN CARES®, 11800 Weston Parkway, Cary, NC 27513, but it will not change any actions taken before I withdraw this authorization. Withdrawal of this authorization will end further uses and disclosures of PHI by the parties identified in this form except to the extent those uses and disclosures have been made in reliance upon this authorization. I understand that I may refuse to sign this form and, if I do so, I will not be able to participate in the PAP, but it will not affect my eligibility to obtain medical treatment, my ability to seek payment for this treatment or affect my insurance enrollment or eligibility for insurance coverage.

Patient Signature _____ Date _____

Please see full Prescribing Information and Patient Information.



What is SOMATULINE® DEPOT (lanreotide) Injection?

SOMATULINE DEPOT is a prescription medicine used in adults for:

- the long-term treatment of people with acromegaly when surgery or radiotherapy have not worked well enough or a patient is unable to have surgery or radiotherapy;
- the treatment of a type of cancer known as neuroendocrine tumors, from the gastrointestinal tract or the pancreas (GEP-NETs) that has spread or cannot be removed by surgery; and
- the treatment of carcinoid syndrome to reduce the need for the use of short-acting somatostatin medicine.

It is not known if SOMATULINE DEPOT is safe and effective in children.

IMPORTANT SAFETY INFORMATION

- **Do not take SOMATULINE DEPOT** if you are allergic to lanreotide.
- **SOMATULINE DEPOT may cause serious side effects**, including:
 - Gallstones
 - Changes to your blood sugar (high or low blood sugar),
 - Slow heart rate, and
 - High blood pressure, and
 - Changes in your thyroid function in acromegaly patients.

Tell your healthcare provider (HCP) if you have any of the following symptoms:

- **Symptoms of gallstones** may include sudden pain in your upper right stomach area (abdomen), sudden pain in your right shoulder or between your shoulder blades, yellowing of your skin and whites of your eyes, fever with chills, and nausea.
- **Symptoms of high blood sugar** may include increased thirst, increased appetite, nausea, weakness or tiredness, urinating more than normal, and fruity smelling breath.
- **Symptoms of low blood sugar** may include dizziness or lightheadedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, irritability or mood changes, and hunger.
- **Symptoms of slow heart rate** may include dizziness or lightheadedness, fainting or near-fainting, chest pain, shortness of breath, confusion or memory problems, and weakness or extreme tiredness.
- SOMATULINE DEPOT can cause the thyroid gland to not make enough thyroid hormone in people with acromegaly. Symptoms of low thyroid levels may include fatigue, weight gain, puffy face, being cold all the time, constipation, dry skin, thinning or dry hair, decreased sweating, and depression.
- **The most common side effects of SOMATULINE DEPOT in people with:**
 - **Acromegaly:** diarrhea; stomach (abdominal) pain; nausea; pain, itching, or a lump at the injection site
 - **GEP-NETs:** stomach area (abdominal) pain; muscle and joint aches; vomiting; headache; pain, itching or a lump at the injection site
 - **Carcinoid syndrome:** headache, dizziness, muscle spasm; side effects were generally similar to those commonly seen with GEP-NETs
- SOMATULINE DEPOT may cause dizziness. If this happens, do not drive a car or operate machinery.
- Tell your HCP right away if you have signs of an allergic reaction after receiving SOMATULINE DEPOT, including swelling of your face, lips or tongue; breathing problems; fainting, dizziness or feeling lightheaded (low blood pressure); itching; skin flushing or redness; rash; or hives.
- **Before taking SOMATULINE DEPOT, tell your HCP about all your medical conditions including if you:** have diabetes; have gallbladder, heart, thyroid, kidney or liver problems; are pregnant or plan to become pregnant; or are breastfeeding or plan to breastfeed. It is not known if SOMATULINE DEPOT will harm your unborn baby or pass into breast milk. You should not breastfeed if you receive SOMATULINE DEPOT and for 6 months after your last dose. SOMATULINE DEPOT may affect your ability to become pregnant.
- **Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SOMATULINE DEPOT and other medicines may affect each other, causing side effects. SOMATULINE DEPOT may affect the way other medicines work, and other medicines may affect how SOMATULINE DEPOT works. Your dose of SOMATULINE DEPOT or your other medications may need to be changed. If you have diabetes, your HCP may change your dose of diabetes medication when you first start receiving SOMATULINE DEPOT or if your dose of SOMATULINE DEPOT is changed.
- **Especially tell your HCP if you take:**
 - Insulin or other diabetes medicines,
 - A cyclosporine (Gengraf, Neoral, or Sandimmune), or
 - Medicines that lower your heart rate, such as beta blockers.

Know the medicines you take. Keep a list of them to show your HCP when you get a new medicine.

Tell your HCP if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of SOMATULINE DEPOT. For more information, ask your HCP.

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



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HEALTHCARE PROVIDER INFORMATION: THIS SECTION MUST BE COMPLETED BY THE PRESCRIBING PHYSICIAN

Prescriber Name _____ Street Address _____
City _____ State _____ Zip _____
DEA# _____ State license # _____
Medicaid provider # _____ Office contact and title _____
Medicare PTAN # _____ Phone (____) _____ Fax (____) _____
Office/Institution _____ Email Address _____
Specialty _____ Preferred method of contact Phone Fax Email
Tax ID # _____ NPI# _____

PRESCRIBER ATTESTATION: By signing below, I certify that a prescription signed by a licensed prescriber is on file for the above therapy and that the patient has provided the necessary authorization to release the above referenced information and medical and/or patient information relating to Somatuline® Depot therapy to Ipsen and its agents or contractors for the purpose of seeking reimbursement for Somatuline® Depot therapy, assisting in initiating or continuing Somatuline® Depot therapy, and/or evaluating the patient's eligibility for Ipsen's patient support programs administered by IPSEN CARES®.

I authorize Ipsen to be my agent and to forward the above prescription, by fax or other mode of delivery, to the pharmacy chosen by the above-named patient. For the state of New York, copies of all prescriptions should be on official New York state prescription forms. I certify that any medications received from Ipsen in connection with any IPSEN CARES® program will be used only for the patient named on this form.

Prescriber Signature _____ Date _____

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.

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 full Prescribing Information and Patient Information.





IMPORTANT SAFETY INFORMATION, CONTINUED

Warnings and Precautions

- **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.

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.

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Somatuline[®] Depot

(lanreotide) Injection

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IPSEN CARES[®]
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