**Patient Information**

**SOMATULINE® DEPOT (So-mah-tu-leen Dee-Poh)**

**(lanreotide) injection**

Read this Patient Information before you receive your first SOMATULINE DEPOT injection and before each injection. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is SOMATULINE DEPOT?**

SOMATULINE DEPOT is a prescription medicine used for:

- the long-term treatment of people with acromegaly when:
  - surgery or radiotherapy have not worked well enough or
  - they are not able to have surgery or radiotherapy
- the treatment of adults with 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
- the treatment of adults with 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.

**Who should not receive SOMATULINE DEPOT?**

**Do not receive SOMATULINE DEPOT if** you are allergic to lanreotide.

**What should I tell my healthcare provider before receiving SOMATULINE DEPOT?**

**Before you receive SOMATULINE DEPOT, tell your healthcare provider about all of your medical conditions, including if you:**

- have gallbladder problems
- have diabetes
- have heart problems
- have thyroid problems
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. It is not known if SOMATULINE DEPOT will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if SOMATULINE DEPOT passes into your breast milk. You should not breastfeed if you receive SOMATULINE DEPOT and for 6 months after your last dose of SOMATULINE DEPOT
- are a female who can become pregnant. SOMATULINE DEPOT may affect fertility in females and may affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you

**Tell your healthcare provider 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 medicines may need to be changed.

Especially tell your healthcare provider if you take:

- insulin or other diabetes medicines
- cyclosporine (Gengraf, Neoral, or Sandimmune)
- medicines that lower your heart rate such as beta blockers

**How will I receive SOMATULINE DEPOT?**

- You will receive a SOMATULINE DEPOT injection every 4 weeks in your healthcare provider's office
- Your healthcare provider may change your dose of SOMATULINE DEPOT or the length of time between your injections. Your healthcare provider will tell you how long you need to receive SOMATULINE DEPOT
- SOMATULINE DEPOT is injected deep under the skin of the upper outer area of your buttock. Your injection site should change (alternate) between your right and left buttock from one injection of SOMATULINE DEPOT to the next
- During your treatment with SOMATULINE DEPOT for acromegaly, your healthcare provider may do certain blood tests to see if SOMATULINE DEPOT is working

**What should I avoid while receiving SOMATULINE DEPOT?**

SOMATULINE DEPOT can cause dizziness. If you have dizziness, do not drive a car or operate machinery.

**What are the possible side effects of SOMATULINE DEPOT?**

**SOMATULINE DEPOT may cause serious side effects, including:**

- **Gallstones (cholelithiasis) and complications that can happen if you have gallstones.** Gallstones are a serious but common side effect in people who take SOMATULINE DEPOT and have acromegaly and GEP-NET. Your healthcare provider may check your gallbladder before and during treatment with SOMATULINE DEPOT. Possible complications of gallstones include inflammation and infection of the gall bladder, and pancreatitis. Tell your healthcare provider if you get any symptoms of gallstones, including:
  - sudden pain in your upper right stomach area (abdomen)
  - yellowing of your skin and whites of your eyes
  - nausea
  - sudden pain in your right shoulder or between your shoulder blades
  - fever with chills
- **Changes in your blood sugar** (high blood sugar or low blood sugar). If you have diabetes, test your blood sugar as your healthcare provider tells you to. Your healthcare provider may change your dose of diabetes medicine especially when you first start receiving SOMATULINE DEPOT or if your dose of SOMATULINE DEPOT changes. High blood sugar is a common side effect in people with GEP-NET.

  Tell your healthcare provider right away if you have any signs or symptoms of high blood sugar or low blood sugar.

  **Signs and symptoms of high blood sugar may include:**
  - increased thirst
  - increased appetite
  - nausea
  - weakness or tiredness
  - urinating more often than normal
  - your breath smells like fruit

  **Signs and symptoms of low blood sugar may include:**
  - dizziness or lightheadedness
  - sweating
  - confusion
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heartbeat
  - irritability or mood changes
  - hunger
- **Slow heart rate.** Tell your healthcare provider right away if you have slowing of your heart rate or if you have symptoms of a slow heart rate, including:
  - dizziness or lightheadedness
  - fainting or near-fainting
  - chest pain
  - shortness of breath
  - confusion or memory problems
  - weakness, extreme tiredness
- **High blood pressure.** High blood pressure can happen in people who receive SOMATULINE DEPOT and is a common side effect in people with GEP-NET.

- **Changes in thyroid function.** SOMATULINE DEPOT can cause the thyroid gland to not make enough thyroid hormones that the body needs (hypothyroidism) in people who have acromegaly. Tell your healthcare provider if you have signs and symptoms of low thyroid hormones levels, including:
  - fatigue
  - weight gain
  - a puffy face
  - being cold all of the time
  - constipation
  - dry skin
  - thinning, dry hair
  - decreased sweating
  - depression

**The most common side effects of SOMATULINE DEPOT in people with acromegaly include:**

- diarrhea
- stomach area (abdominal) pain
- nausea
- pain, itching, or a lump at the injection site

**The most common side effects of SOMATULINE DEPOT in people with GEP-NET include:**

- stomach area (abdominal) pain
- muscle and joint aches
- vomiting
- headache
- pain, itching, or a lump at the injection site

**The most common side effects of SOMATULINE DEPOT in people with carcinoid syndrome include:**

- headache
- dizziness
- muscle spasm

Tell your healthcare provider right away if you have signs of an allergic reaction after receiving SOMATULINE DEPOT, including:

- swelling of your face, lips, mouth or tongue
- breathing problems
- fainting, dizziness, feeling lightheaded (low blood pressure)
- itching
- flushing or redness of your skin
- rash
- hives

These are not all the possible side effects of SOMATULINE DEPOT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of SOMATULINE DEPOT.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not receive SOMATULINE DEPOT for a condition for which it was not prescribed. You can ask your healthcare provider for information about SOMATULINE DEPOT that is written for health professionals.

**What are the ingredients in SOMATULINE DEPOT?**

**Active ingredient:** lanreotide acetate

**Inactive ingredients:** water for injection and acetic acid (for pH adjustment)

Manufactured by: Ipsen Pharma Biotech, Parc d'Activities du Plateau de Signes, 83870 Signes, France

Manufactured for: Ipsen Biopharmaceuticals, Inc., 1 Main Street, Unit 700, Cambridge, MA 02142 USA.

For more information, go to www.somatulinedepot.com or call Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 6/2019