

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 professional 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 people 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

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

Who should not take SOMATULINE DEPOT?

Do not take SOMATULINE DEPOT if you are allergic to lanreotide.

What should I tell my healthcare professional before receiving SOMATULINE DEPOT?

Before you receive SOMATULINE DEPOT, tell your healthcare professional if you:

- have gallbladder problems
- have diabetes
- have thyroid problems
- have heart problems
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. SOMATULINE DEPOT may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SOMATULINE DEPOT passes into your breast milk. You and your healthcare professional should decide if you will take SOMATULINE DEPOT or breastfeed. You should not do both.

Tell your healthcare professional 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 adjusted.

Especially tell your healthcare professional if you take:

- insulin or other diabetes medicines
- a cyclosporine (Gengraf, Neoral, or Sandimmune)
- a medicine called bromocriptine (Parlodel, Cycloset)
- medicines that lower your heart rate such as beta blockers

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

How will I receive SOMATULINE DEPOT?

- You will receive a SOMATULINE DEPOT injection every 4 weeks in your doctor's office.
- Your prescriber may change your dose of SOMATULINE DEPOT or the length of time between your injections. Your healthcare professional 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 professional may do certain blood tests to see if SOMATULINE DEPOT is working.

What are the possible side effects of SOMATULINE DEPOT?

SOMATULINE DEPOT may cause serious side effects, including:

- **Gallstones.** Tell your healthcare professional if you get any of these symptoms:
 - 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
 - nausea
- **Changes in your blood sugar** (high blood sugar or low blood sugar). If you have diabetes, test your blood sugar as your healthcare professional tells you to. Your healthcare professional may change your dose of diabetes medicine especially when you first start receiving SOMATULINE DEPOT or if your dose of SOMATULINE DEPOT changes.
- **Slow heart rate**
- **High blood pressure**

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-NETs include:

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

SOMATULINE DEPOT may cause dizziness. If this happens, do not drive a car or operate machinery.

Tell your healthcare professional 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 healthcare professional.

Call your healthcare professional 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 conditions other than those listed in the patient leaflet. This Patient Information leaflet summarizes the most important information about SOMATULINE DEPOT. If you would like more information about SOMATULINE DEPOT, talk with your healthcare professional. You can ask your healthcare professional for information about SOMATULINE DEPOT that is written for health professionals.

For more information, go to www.somatulinedepot.com or call Ipsen Biopharmaceuticals, Inc. at 1-866-837-2422.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 12/2014

SOMATULINE DEPOT is manufactured by Ipsen Pharma Biotech, Parc d'Activites du Plateau de Signes, 83870 Signes, France for Ipsen Biopharmaceuticals, Inc., 106 Allen Road, Basking Ridge, NJ 07920 USA.