

What is Somatuline[®] Depot (lanreotide) Injection?

Somatuline Depot is a prescription medicine used for:

- Long-term treatment of adults with acromegaly when surgery or radiotherapy has not worked well enough or the patient is not able to have surgery or radiotherapy.
- 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.

It is not known if Somatuline Depot is safe and effective in children.

You will receive a Somatuline Depot injection in your doctor's office. 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 to the next.

Important Safety Information

Who should not take Somatuline Depot?

Do not take Somatuline Depot if you are allergic to lanreotide.

Somatuline Depot may cause serious side effects including:

- Gallstones
- Changes in your blood sugar (high blood sugar or low blood sugar)
- Slow heart rate
- High blood pressure

The most common side effects of Somatuline Depot in:

- People with acromegaly include diarrhea, gallstones, stomach area (abdominal) pain, nausea, and pain, itching, or a lump at the injection site.
- People with GEP-NETs include stomach area (abdominal) pain, muscle and joint aches, vomiting, headache, and pain, itching, or a lump at the injection site.

These are not all the possible side effects of Somatuline Depot. Tell your doctor if you have any side effect that bothers you or that does not go away.

Before you receive Somatuline Depot, talk to your doctor about:

All of your medical conditions, including

- Gallbladder, heart, thyroid, kidney, or liver problems
- Diabetes
- Pregnancy or plans to become pregnant
 - It is not known if Somatuline Depot could harm your unborn baby
- Breast-feeding or plans to breast-feed
 - It is not known if Somatuline Depot passes into breast milk

Any medicines (prescription and nonprescription) you are taking, including

- Insulin or other diabetes medicines
- A cyclosporine (such as Gengraf[®], Neoral[®], or Sandimmune[®])
- A medicine called bromocriptine (such as Parlodel[®] or Cycloset[®])
- Medicines that lower your heart rate (such as beta blockers)

You may report suspected adverse reactions to FDA at 1-800-FDA-1088 or to Ipsen Biopharmaceuticals, Inc. at 1-888-980-2889.