

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 doctor 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

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

What should I tell my doctor before receiving Somatuline[®] Depot?

Before you receive Somatuline[®] Depot, tell your doctor if you have:

- gallbladder problems
- diabetes
- thyroid problems
- heart problems
- kidney problems
- liver problems
- are allergic to latex or natural dry rubber. The prefilled syringe needle cover contains rubber.
- are pregnant or plan to become pregnant. It is not known if Somatuline[®] Depot will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if Somatuline[®] Depot passes into your breast milk. Talk to your doctor about the best way to feed your baby if you receive Somatuline[®] Depot.

Tell your doctor about all the medicines you take, including prescription and non-prescription 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 doctor if you take:

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

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

How will I receive Somatuline[®] Depot?

- You will receive a Somatuline[®] Depot injection every 4 weeks as directed by your doctor. Your doctor may change your dose of Somatuline[®] Depot or the length of time between injections. Your doctor 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 each time you receive an injection of Somatuline[®] Depot.
- During your treatment with Somatuline[®] Depot, your doctor may do certain blood tests to see if Somatuline[®] Depot is working. Your doctor may change your dose or length of time between your Somatuline[®] Depot injections as needed.

What are the possible side effects of Somatuline[®] Depot?

Somatuline[®] Depot may cause serious side effects, including:

- **gallstones.** Tell your doctor if you have 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 doctor tells you to. Your doctor 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 include:

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

Tell your doctor 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 doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the 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 doctor. You can ask your pharmacist or doctor 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.

Somatuline[®] Depot is manufactured by Ipsen Pharma Biotech SAS BP, 707 Signes, 83030 Toulon Cedex 9, France for Ipsen Pharma SAS, 65 quai Georges Gorse, 92650, Boulogne Billancourt Cedex, France.