

Somatuline Depot Acromegaly and Oncology Consumer Indication and ISI September 2017

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**,
 - **High blood pressure**, and
 - **Changes in 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 click here for the full Prescribing Information and Patient Information.