



Somatuline® (lanreotide) Backgrounder

Somatuline® Depot® (lanreotide) 120mg injection was approved by the U.S. Food and Drug Administration (FDA) for the treatment of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. Somatuline® is administered using a single-dose pre-filled syringe that eliminates the need for reconstituting the medication while supporting full-dose delivery.

What is Somatuline®?

Somatuline® belongs to a class of drug known as somatostatin analogs. It is a manmade hormone which may reduce the overproduction of hormones active in the disease.

It is the first drug of its class to demonstrate progression-free survival and the first and only somatostatin analog to receive approval as an antitumor therapy. The approval comes at the conclusion of a priority review by the FDA.

In the United States, Somatuline® Depot® is also indicated for the long-term treatment of patients with acromegaly who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy.

Somatuline® Depot® does not require reconstitution and is to be delivered via a newly approved, ready-to-use, single-dose prefilled syringe incorporating Safe'n'Sound® technology. Somatuline® Depot® is a low volume (0.5 mL) deep subcutaneous injection offering a streamlined process that supports full dose delivery. With healthcare professionals in mind, Safe'n'Sound® syringe technology includes a retractable guard to help avoid needle sticks, and it is also manufactured without latex or natural dry rubber.

Important Safety Information

Somatuline® Depot® may cause serious side effects including: gallstones, changes in blood sugar (high blood sugar or low blood sugar), slow heart rate and high blood pressure. The most common side effects of Somatuline® Depot® include diarrhea, gallstones, stomach area (abdominal) pain, nausea, and pain, itching, or a lump at the injection site. These are not all the possible side effects of Somatuline® Depot®. For a full list of potential adverse events and the full prescribing information, please refer to the label.