

Lanreotide injection – New drug approval

- On December 19, 2021, [Cipla Limited announced](#) the [FDA approval](#) of [Lanreotide injection](#), for the:
 - Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal.
 - Treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.
- Lanreotide injection was approved via the 505(b)(2) New Drug Application pathway and the active ingredient, route of administration and strengths are the same as [Somatuline Depot®](#).
 - In addition to acromegaly and GEP-NETs, Somatuline Depot is also approved for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
- Warnings and precautions for Lanreotide injection include cholelithiasis and complications of cholelithiasis; hyperglycemia and hypoglycemia; cardiovascular abnormalities; thyroid function abnormalities; and monitoring laboratory tests.
- The most common adverse reactions (> 5%) with Lanreotide injection use for acromegaly are diarrhea, cholelithiasis, abdominal pain, nausea, and injection site reactions.
- The most common adverse reactions (> 10%) with Lanreotide injection use for GEP-NET are abdominal pain, musculoskeletal pain, vomiting, headache, injection site reaction, hyperglycemia, hypertension, and cholelithiasis.
- The recommended starting dosage of Lanreotide Injection for acromegaly is 90 mg given via the deep subcutaneous (SC) route, at 4-week intervals for 3 months. After 3 months, the Lanreotide injection dosage may be adjusted as follows:
 - GH greater than 1 ng/mL to less than or equal to 2.5 ng/mL, IGF-1 normal, and clinical symptoms controlled: maintain dosage at 90 mg every 4 weeks
 - GH greater than 2.5 ng/mL, IGF-1 elevated, and/or clinical symptoms uncontrolled: increase dosage to 120 mg every 4 weeks
 - GH less than or equal to 1 ng/mL, IGF-1 normal, and clinical symptoms controlled: reduce dosage to 60 mg every 4 weeks
 - Thereafter, the dosage should be adjusted according to the response of the patient as judged by a reduction in serum GH and/or IGF-1 levels; and/or changes in symptoms of acromegaly.
- The recommended dosage of Lanreotide Injection for GEP-NET is 120 mg administered every 4 weeks by deep SC injection.
- Lanreotide injection is intended for administration by a healthcare provider.

- Cipla's launch plans for Lanreotide injection are pending. Lanreotide injection will be available as 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL single-dose prefilled syringes.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.