

Lanreotide Formulation and Device

Information on the Handling and Administration of Lanreotide ADVANZ PHARMA 60 mg, 90 mg or 120 mg solution for injection in a prefilled syringe is briefly summarized below and subsequently discussed in more detail.

Lanreotide ADVANZ PHARMA 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) on 23 November 2023 following a decentralised procedure with Denmark as Reference Member state [1,2].

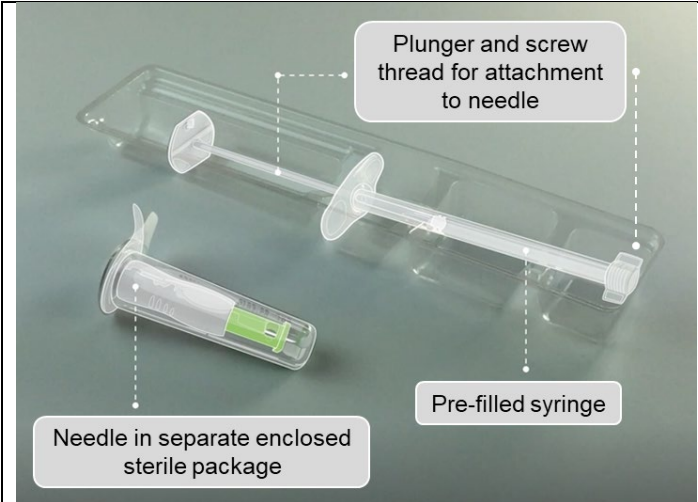
Lanreotide ADVANZ PHARMA is indicated for [2]:

- The treatment of individuals with acromegaly when the circulating levels of Growth Hormone (GH) and/or Insulin-like Growth Factor-1 (IGF-1) remain abnormal after surgery and/or radiotherapy, or in patients who otherwise require medical treatment.
- The treatment of grade 1 and a subset of grade 2 (Ki67 index up to 10%) gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients with unresectable locally advanced or metastatic disease.
- The treatment of symptoms associated with neuroendocrine (particularly carcinoid) tumours.

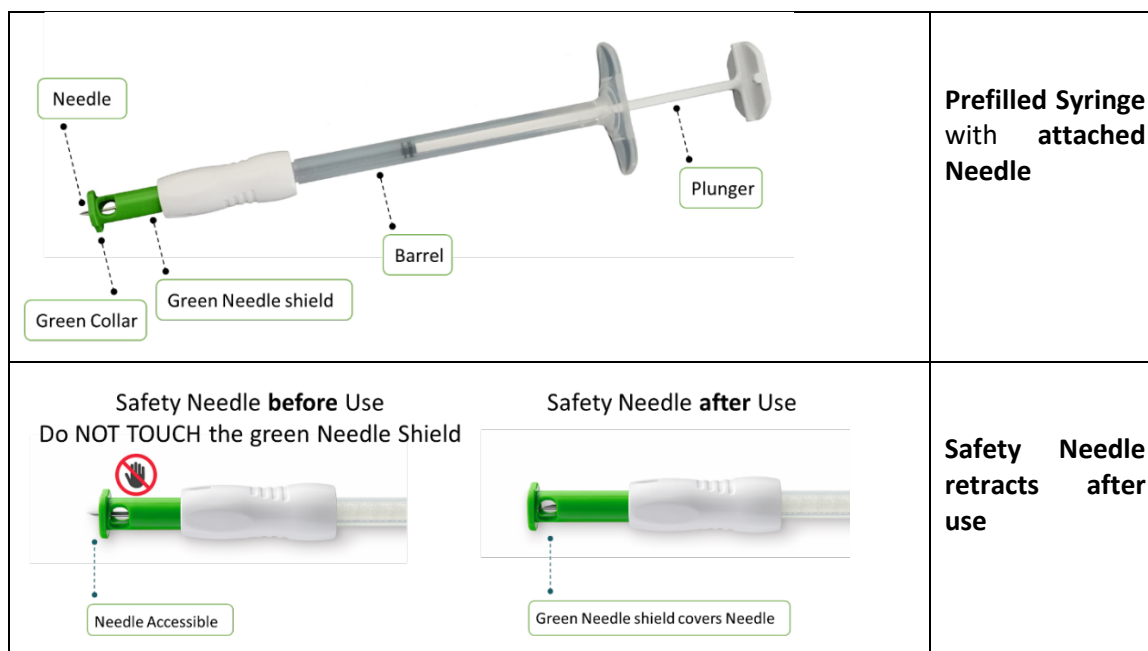
SUMMARY

- Lanreotide ADVANZ PHARMA 60 mg, 90 mg and 120 mg solution for injection is supplied in a prefilled syringe and contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg lanreotide base/mg of solution, which ensures an actual injection dose of 60 mg, 90 mg or 120 mg of lanreotide, respectively [2].
- Lanreotide must be stored in a refrigerator at 2°C to 8°C in the original package in order to protect from light. The pre-filled syringe has a shelf-life of 2 years.

➤ Lanreotide device - Nature and contents of container

 Plunger and screw thread for attachment to needle Pre-filled syringe Needle in separate enclosed sterile package	Lanreotide is supplied [2] in a pre-filled syringe (polypropylene with thermoplastic elastomer rubber plunger stopper sealed with polypropylene cap) placed in a plastic tray and sealed inside an aluminum pouch and a separately packed automatic single use needle-safe device. Needle pack and Syringe are packaged inside a cardboard box.
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Lanreotide ADVANZ PHARMA is supplied in a box of one 0.5 mL pre-filled syringe with one co-packaged safety needle (1.2 mm x 20 mm).



The solution for injection in a pre-filled syringe is ready for use. Please refer to the Summary of Product Characteristics and the Patient Information Leaflet for detailed instructions for use.

➤ Lanreotide formulation

Lanreotide acetate 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe and contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg lanreotide base/mg of solution, which ensures an actual injection dose of 60 mg, 90 mg or 120 mg of lanreotide, respectively [2].

Excipients are water for injections and glacial acetic acid (for pH adjustment).

This formulation is based on the property of lanreotide supersaturated solutions to spontaneously self-assemble into nanotubes in water, forming a gel with controlled release properties when injected subcutaneously to a patient [2; 3; 4; 5].

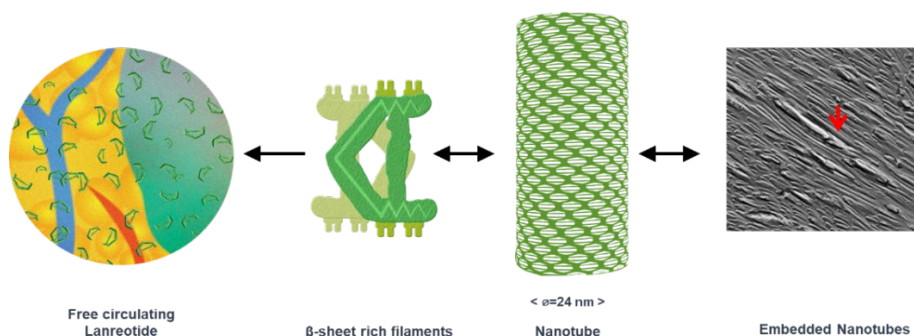
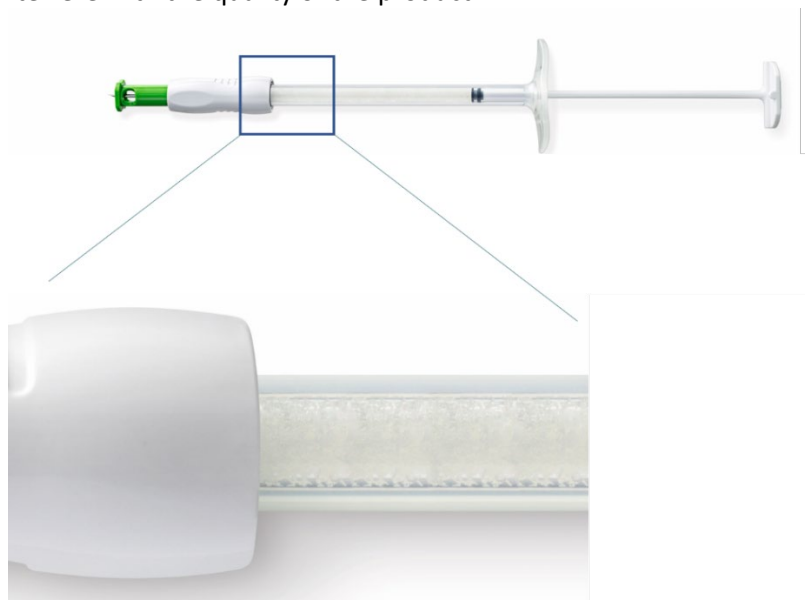


Figure 1. The conformation of Lanreotide acetate in water at room temperature is concentration-dependent. At low concentration, lanreotide forms soluble β -sheet filaments. These structures are precursors of tubular structures. At intermediate concentrations, nanotubes are formed, which organize at higher concentrations into embedded nanotubes forming a gel. [4; 5; 6]

➤ Nature of the Lanreotide acetate gel

The content of the prefilled syringe is a **semi-solid phase** having a **gel-like appearance, with viscous characteristics** and a colour varying from **white to pale yellow**. The supersaturated solution **can also contain micro bubbles** that can clear up during injection. These differences are normal and do not interfere with the quality of the product.



The left-hand picture illustrates appearance of the lanreotide acetate gel as example only, colour may vary from white to pale yellow.

The information contained in this medical letter is supplied as a medical information service by ADVANZ PHARMA in response to your specific request. ADVANZ PHARMA only recommends the use of lanreotide as specified in the prescribing information officially approved by the regulatory authority of your country. For complete information on lanreotide, please refer to the approved prescribing information.

Last revision: 28 January 2023

References

1. Mytolac (Lanreotide) 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe. Decentralised Procedure, DK/H/3027/001-003/DC
2. Lanreotide ADVANZ PHARMA 60 mg, 90 mg or 120 mg solution for injection in a prefilled syringe, Summary of Product Characteristics, Medicines and Healthcare products Regulatory Agency (MHRA)
3. Wolin EM, Manon A, Chassaing C, Lewis A, Bertocchi L, Richard J, Phan AT. Lanreotide Depot: An Antineoplastic Treatment of Carcinoid or Neuroendocrine Tumors. J Gastrointest Cancer. 2016 Dec;47(4):366-374. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc5138269/>; <https://doi.org/10.1007/s12029-016-9866-9>
4. Valéry C, Paternostre M, Robert B, Gulik-Krzywicki T, et al. Biomimetic organization: Octapeptide self-assembly into nanotubes of viral capsid-like dimension. Proc Natl Acad Sci U S A. 2003 Sep 2;100(18):10258-62. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc193548/>; <https://doi.org/10.1073/pnas.1730609100>

5. Valéry C, Artzner F, Robert B, Gulick T, et al. Self-association process of a peptide in solution: from beta-sheet filaments to large embedded nanotubes. Biophys J. 2004 Apr;86(4):2484-501. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc1304096/>; [https://doi.org/10.1016/s0006-3495\(04\)74304-0](https://doi.org/10.1016/s0006-3495(04)74304-0)
6. Data on file. Sameness Study of Lanreotide acetate LAI and Somatuline – Supramolecular structure.