

Lanreotide Formulation and Device

Information on the Formulation and Device 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].

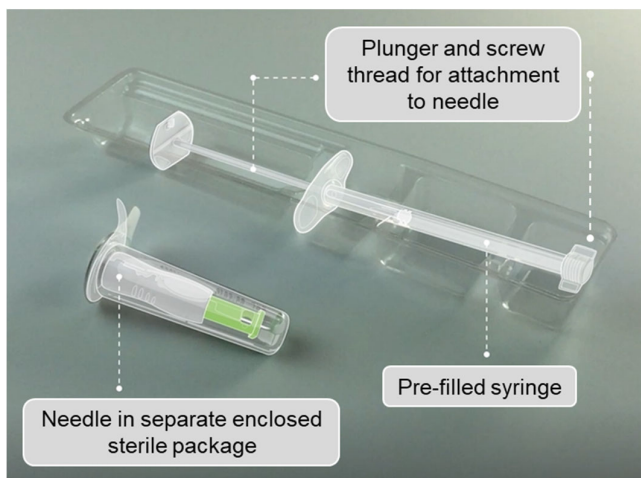
Lanreotide ADVANZ PHARMA is indicated for [2]:

- 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.

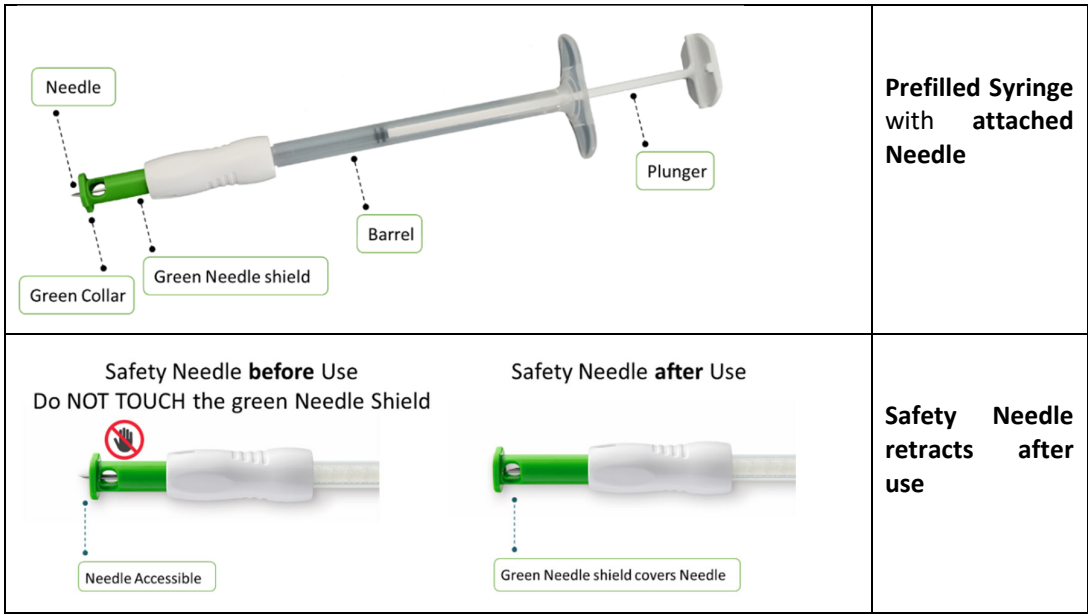
➤ Lanreotide device - Nature and contents of container



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.

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 safety needle is not commercialized individually.



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 deep subcutaneously to a patient [2; 3; 4; 5].

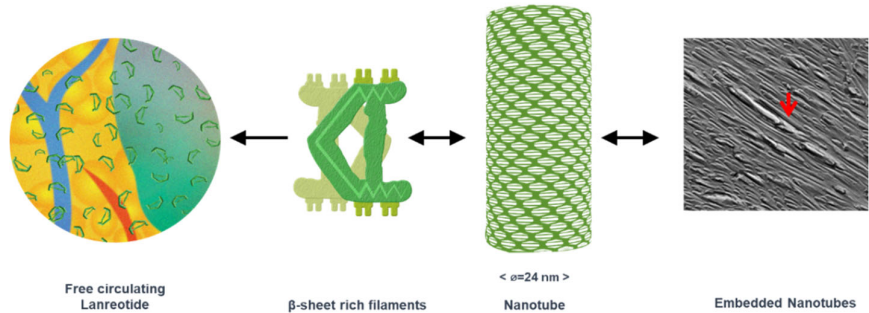
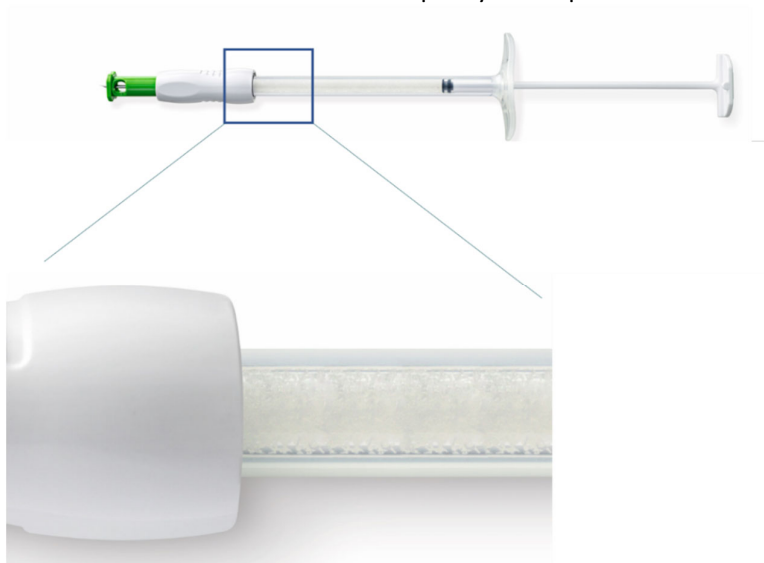


Figure 1. The conformation of Lanreotide acetate in water at room temperature is concentration-dependent. At low concentration, lanreotide forms soluble β -sheet filaments. These structures are precursors of tubular structures. At

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 or vacant spaces** 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.

As noted above, vacant spaces can be present in the syringes due to its highly viscous nature of the gel. If the totality of the gel contained in the prefilled syringe is injected, the patient is administered a full dose.

The Lanreotide ADVANZ PHARMA syringe is not graduated and it is therefore only intended to administer a complete dose.

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: 21 June 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
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Dec;47(4):366-374. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc5138269/>;
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