

Lanreotide Technical and Allergen Information

Lanreotide ADVANZ PHARMA (Lanreotide acetate) 60 mg, 90 mg and 120 mg solution for injection in a prefilled syringe is indicated for [1]:

- 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.

➤ Relevant Information from the Summary of Product Characteristics (SmPC) [1]

2. Qualitative and quantitative composition

Lanreotide (I.N.N.), 120 mg (as acetate)

Each prefilled syringe contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg lanreotide base/mg of solution, which ensures an actual injection dose of 120 mg of lanreotide.

For the full list of excipients, see section 6.1.

6.1 List of excipients

Water for injections.

Glacial acetic acid (for pH adjustment)

6.5 Nature and contents of container

Lanreotide ADVANZ PHARMA solution for injection is supplied 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. Both are packaged inside a cardboard box.

Box of one 0.5 mL syringe with one co-packaged safety needle (1.2 mm x 20 mm).

Not all pack sizes may be marketed.

➤ Additional Information [2]

Is Lanreotide ADVANZ PHARMA Suitable for Vegetarians/Vegans?

Yes, Lanreotide is suitable for vegetarians and vegans.

Does Lanreotide ADVANZ PHARMA contain gelatine?

No, Lanreotide ADVANZ PHARMA does not contain gelatine.

Does Lanreotide ADVANZ PHARMA contain gluten?

No, Lanreotide ADVANZ PHARMA does not contain gluten.

Does Lanreotide ADVANZ PHARMA contain sodium?

No, Lanreotide ADVANZ PHARMA does not contain sodium.

Does Lanreotide ADVANZ PHARMA contain lactose?

No, Lanreotide ADVANZ PHARMA does not contain lactose.

Does Lanreotide ADVANZ PHARMA contain nuts?

No, Lanreotide ADVANZ PHARMA does not contain nuts.

Does Lanreotide ADVANZ PHARMA contain preservatives?

No, Lanreotide ADVANZ PHARMA does not contain preservatives.

Is Lanreotide ADVANZ PHARMA sugar free?

Yes, Lanreotide ADVANZ PHARMA does not contain sugar

Does Lanreotide ADVANZ PHARMA contain latex?

No, Lanreotide ADVANZ PHARMA does not contain latex, however contact with latex during or after manufacture cannot be excluded.

What is the pH of the Lanreotide ADVANZ PHARMA injection?

Lanreotide solution has a pH of 5.5-6.5

The information contained in this medical letter is supplied as a medical information service by ADVANZ PHARMA in response to your specific request. Information provided by ADVANZ Pharma Medical Information should be viewed at all times alongside the SmPC. It should not constitute formal clinical advice. 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 the safety of lanreotide, please refer to the approved prescribing information.

Last revision: 27 June 2023

References

1. Lanreotide ADVANZ PHARMA 60 mg, 90 mg or 120 mg solution for injection in a prefilled syringe, Medicines and Healthcare products Regulatory Agency (MHRA), Summary of Product Characteristics; available at <https://www.medicines.org.uk/emc/product/14483/smpc> (60mg); <https://www.medicines.org.uk/emc/product/14484/smpc> (90mg); <https://www.medicines.org.uk/emc/product/14485/smpc> (120mg); last access: 21 June 2023
2. ADVANZ PHARMA, data on file