

*****TEST DOCUMENT 002*****

UPDATED VERSION

Lanreotide Storage and Stability

Keywords: *stability, storage, expiry, temperature, cooling, refrigerator, freezing, heating, light, photostability, shelf life*

Please provide extended stability data only when a temperature excursion has taken place, and obtain the parameters of the excursion, i.e. maximum/minimum temperature, time period of exposure. According to the parameters of the excursion, please provide the appropriate information from the below data. For any other temperature excursions there is no supportive stability data and the product needs to be discarded.

For prospective extended stability request, i.e. without an actual temperature excursion, please use "FAQ_General_Prospective Extended Stability Request"

Shelf life: of ADVANZ PHARMA's lanreotide acetate, solution for injection [1, 2]

- **Unopened product:** is 2 years.

Opened Product: In-use shelf-life information is not available; Remove the lanreotide prefilled syringe from the refrigerator 30 minutes prior to injecting. Keep the laminated pouch sealed until just before the injection. After opening the protective aluminum pouch, the product should be administered immediately.

Storage: This medicinal product should be stored in a refrigerator (2°C – 8°C) in the original package in order to protect from light. The product can, provided it has been stored in the sealed pouch at a maximum temperature of 40 °C for up to a total of 24 hours, be restored in the refrigerator (the number of temperature fluctuations must not exceed three) for continued storage and later use. [1]

Photostability: This medicinal product should be in the original package in order to protect from light.

Special precautions for disposal and other handling: The used injection device should be disposed of in a designated sharps container. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. [1]

Temperature excursion

High temperature: stable for 72 hours at 40°C. This is the maximum temperature, if this is exceeded, the product must be discarded.

Product: Lanreotide acetate (Mytolac, Myrelez, or Mytolente in EU; Lanreotide ADVANZ PHARMA in UK) v3.0 N/A Label Approval: February 2024

Freezing: stable for up to 72 hours at -20°C. This is the minimum temperature, if this is exceeded, the product must be discarded.

Please **do not** indicate on general requests this stability information, but only answer on requests on specific excursions with available batch number/expiration date/number of impacted syringes.

Answer: (please fill in/select the yellow highlight parts according to the request with either the paragraph on high temperature or freezing and select the appropriate product name)

As per the Mytolac/Myrelez/Mytolente/Lanreotide ADVANZ PHARMA (Lanreotide) 60 mg, 90 mg, 120 mg solution for injection in a prefilled syringe, Summary of product Characteristics, the registered storage conditions are as follows.

Section 6.4 Special precautions for storage

This medicinal product should be stored in a refrigerator (2°C – 8°C) in the original package in order to protect from light.

The product can, provided it has been stored in the sealed pouch at a maximum temperature of 40 °C for up to a total of 24 hours, be restored in the refrigerator (the number of temperature fluctuations must not exceed three) for continued storage and later use.

High temperature

Supporting Information:

Based on the acceptable stability data for Mytolac/Myrelez/Mytolente/Lanreotide ADVANZ PHARMA (Lanreotide) 60 mg, 90 mg, 120 mg solution for injection in a prefilled syringe, the temperature deviation for maximal XX hours at maximal xx°C has no impact on the quality of the product and can be used.

Batch number: XXXXX

Exp date: XX/20XX

Excursion: maximal XX hours at less than XX °C

If the temperature excursion was above 40°C, the product should be discarded.

Freezing

Supporting Information:

Based on the acceptable stability data for Mytolac/Myrelez/Mytolente/Lanreotide ADVANZ PHARMA (Lanreotide) 60 mg, 90 mg, 120 mg solution for injection in a prefilled syringe, the temperature deviation for maximal XX hours at minimal xx°C has no impact on the quality of the product and can be used.

Batch number: XXXXX

Exp date: XX/20XX

Excursion: maximal XX hours at not less than -XX °C

If the temperature excursion was below -20°C, the product should be discarded.

References :

Product: Lanreotide acetate (Mytolac, Myrelez, or Mytolente in EU; Lanreotide ADVANZ PHARMA in UK) v3.0 N/A Label Approval: February 2024

1. *Mytolac/Myrelez/Mytolente/Lanreotide ADVANZ PHARMA (please select according to country)* (Lanreotide) 60 mg, 90 mg, 120 mg solution for injection in a prefilled syringe, Summary of product Characteristics (SmPC)
2. *Mytolac/Myrelez/Mytolente/Lanreotide ADVANZ PHARMA (please select according to country)* (Lanreotide) 60 mg, 90 mg, 120 mg solution for injection in a prefilled syringe, Lanreotide Patient Information Leaflet (PIL)