

Lanreotide Patient Guide for Handling and Administration

Lanreotide ADVANZ PHARMA (Lanreotide acetate) 60 mg, 90 mg and 120 mg solution for injection in a pre-filled syringe is, depending on the country, marketed under the brand names Mytolac, Myrelez, Mytolente, or Lanreotide ADVANZ PHARMA.

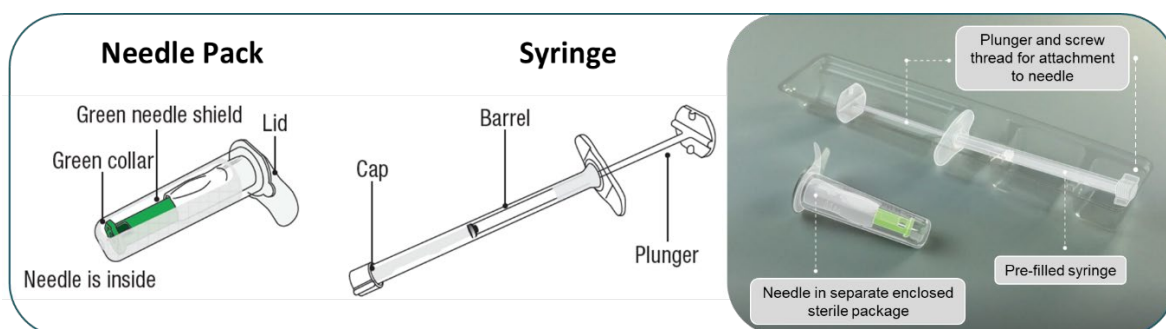
ADVANZ PHARMA's Lanreotide is indicated for [1]:

- 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.

Please read all of the Patient Information Leaflet [2] carefully before you start using this medicine because it contains important information for you.

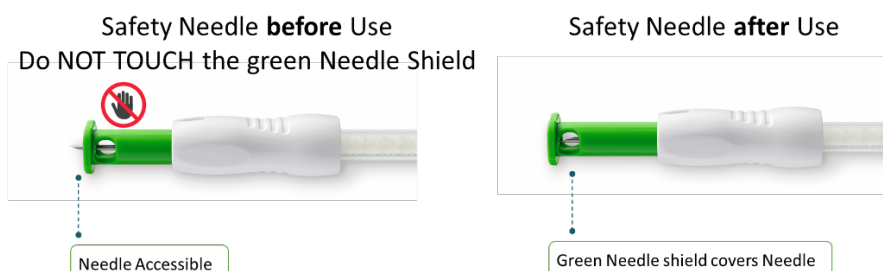
➤ Nature and contents of container and Composition [1]

Lanreotide 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-safety device.



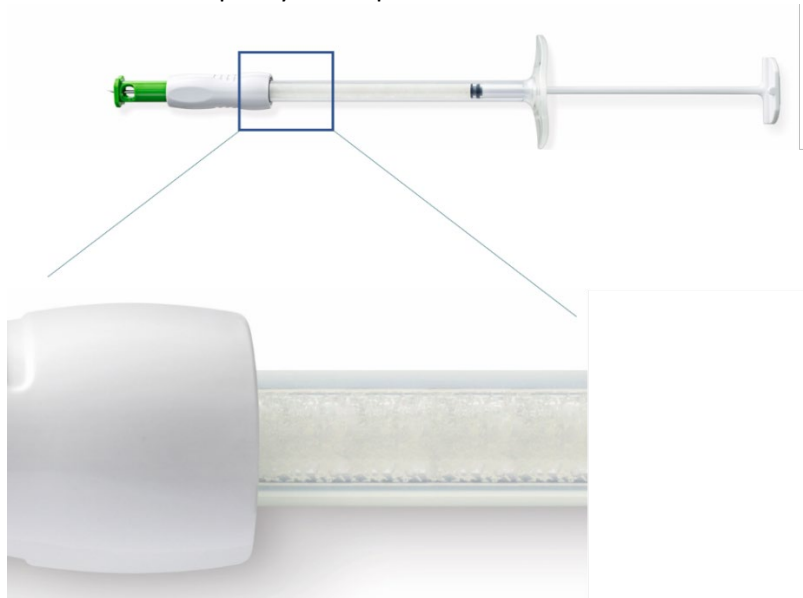
Needle pack and Syringe are packaged inside a cardboard box.

- Box of one 0.5 mL syringe with one co-packaged safety needle (1.2 mm x 20 mm).
- Multipack with 3 boxes



➤ 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 possible appearance of the lanreotide acetate gel as example only, colour varying from white to pale yellow. Check with your doctor or pharmacist if you are not sure.

➤ Storage and Stability of Lanreotide [1]

Store in a refrigerator (2 – 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.

Shelf life is 2 years. After opening the protective aluminum pouch, the product should be administered immediately.

➤ Instructions for use [according to Refs 1, 2]

For immediate and single use following first opening. Do not use if the pouch is damaged, opened or if the medication has expired.

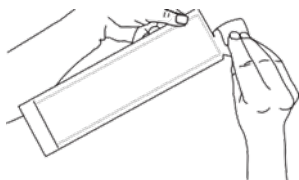
It is important that the injection of the product is performed exactly according to the instructions in the package leaflet. Please read all the instructions carefully before starting the injection. The injection is a deep subcutaneous injection that requires a specific technique different to normal subcutaneous injections.

Remove lanreotide prefilled syringe from the refrigerator 30 minutes prior to injecting. This allows the lanreotide solution to reach room temperature, to minimize pain reaction to cold medication. Keep the laminated pouch sealed until just before the injection.



30 Minutes

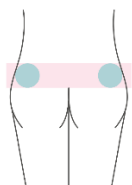
1. Make sure there is a clean surface for preparation.
3. Choose injection site - the sites are shown below.
4. Wash hands and clean the injection site as per the instructions in the package leaflet.



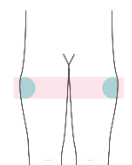
Tear open the pouch and take out the pre-filled syringe.

After opening the protective laminated pouch, the product should be administered immediately.

Lanreotide is administered by deep subcutaneous injection in the superior external quadrant of the buttock or in the upper outer thigh. For patients who receive a stable dose, the product may be administered either by the patient or a third party after careful training and in agreement with the responsible physician and/or nurse.



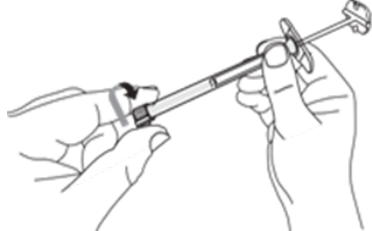
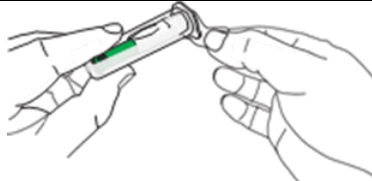
If you are injecting someone else: Inject into the upper outer area of the **buttock**

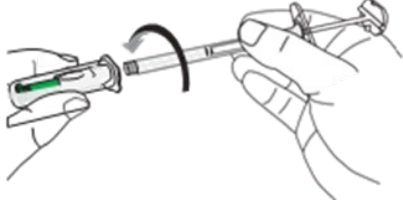
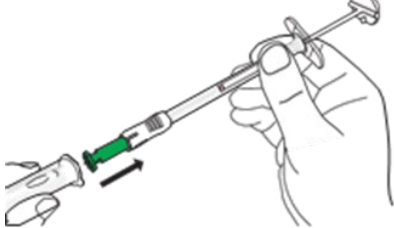
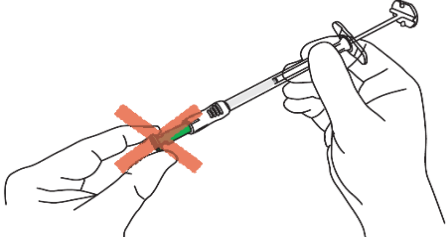


If you are injecting yourself: Inject into the upper outer part of your **thigh**

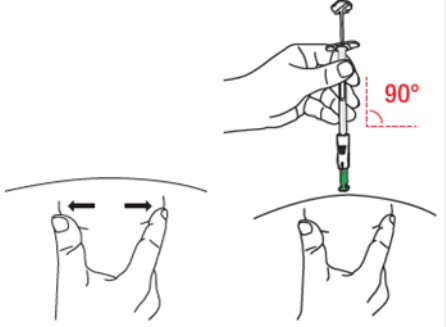
Caution: Choose well the injection site for appropriate administration. If possible, avoid damaged tissue and vary the administration site from side to side (left and right) over time.

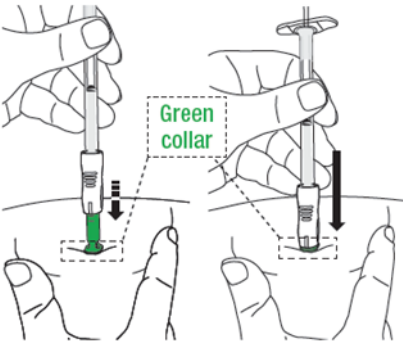
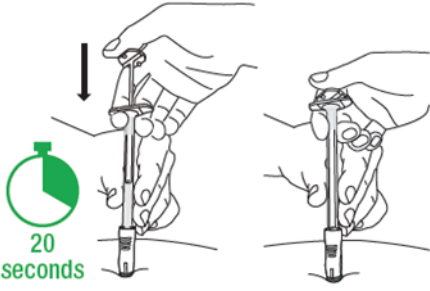
Preparation of the syringe

	Remove the cap from the syringe • With one hand, hold the syringe barrel steady (not the plunger). • With the other hand, remove the cap by twisting it.
	Open the needle pack • Hold the needle pack and pull the lid off. Caution: Do not touch the open end of the needle pack. This needs to stay sterile.

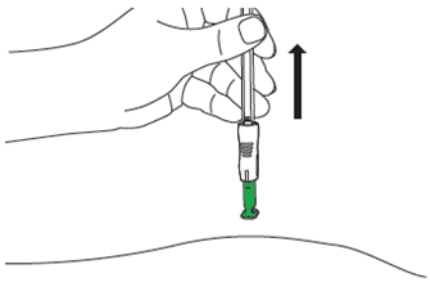
	Put the end of the syringe into open end of the needle pack • Hold the needle pack with one hand. • With the other, hold the syringe barrel steady (not the plunger) and twist until the syringe and needle are fully locked together. • Maintain both needle pack and syringe barrel straight when screwing • They are fully locked when you cannot turn it any further. Important: Tighten the syringe firmly to avoid drug leakage.
	Remove the needle from the pack • Hold the syringe barrel (not the plunger). • Pull the needle straight out from the needle pack without twisting or turning to make sure that the syringe is well connected to the safety needle. Caution: Partially exposed needle from this step onwards. Important: DO NOT touch the green needle shield
DO NOT TOUCH THE GREEN NEEDLE SHIELD. THIS IS NOT A CAP. 	• NEVER TOUCH OR TRY TO OPEN THE GREEN NEEDLE SHIELD • GREEN NEEDLE SHIELD is NOT a removable cap or cover for the needle. • GREEN NEEDLE SHIELD will automatically activate during the needle insertion and then automatically cover and lock around the needle once the injection is complete. • GREEN NEEDLE SHIELD is a self-operating safety lock mechanism.

Perform Injection

	Position the syringe To check which site you should use, refer to section B. Stretch the skin around the injection site flat and tight using your thumb and index finger. Do not pinch the skin. Hold the lower part of the syringe barrel (not the plunger) with your other hand. • Position the syringe at a 90-degree angle to the skin
---	--

	Insert the needle Without folding or pressing on the skin at the injection site, push the needle firmly against the skin while keeping hold of the syringe barrel. The green safety shield will retract. Important: continue to press evenly and consistently until the green safety shield is pushed into the white socket, only the thin collar of the safety shield should be visible. Avoid pulling the needle back/outward before the injection is completed, as the safety functions may be triggered prematurely. DO NOT push the plunger in this step. Hold the syringe in this position for the next step
	Push the top of the plunger Move your hand from the skin to the plunger Important: do not release the pressure, the green safety shield should remain covered. Push the plunger slowly but steady with very firm pressure without interruption until the top touches the syringe barrel (it is easier to depress the plunger with your dominant hand). The medication is thicker and harder to push than you might expect. Inject the full dose and give a final push to make sure you cannot depress it any further. This should take around 20 seconds.

Remove and throw away syringe

	Remove from the skin Lift the syringe straight up and away from your body. The green needle shield will cover the needle.
	Apply gentle pressure - Apply gentle pressure to the injection site with a dry cotton ball or sterile gauze to prevent any bleeding. Do not rub or massage the injection site after administration

➤ Disposal [2]

Dispose of the used syringe and needle according to your local laws and regulations or how your doctor has shown you.

The needles are not reusable.

Do not dispose of the syringe or needle in your general household rubbish.

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 patient information leaflet. It should not constitute formal clinical advice. Always use this medicine exactly as your doctor has told you. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Last revision: 28 November 2022

References

1. Mytolac / Myrelez / Mytolente (Lanreotide [I.N.N.]), 60 mg, 90 mg or 120 mg (as acetate) solution for injection in a prefilled syringe, Summary of Product Characteristics
2. Mytolac / Myrelez / (Lanreotide [I.N.N.]), 60 mg, 90 mg or 120 mg (as acetate) solution for injection in a prefilled syringe, Patient Information Leaflet