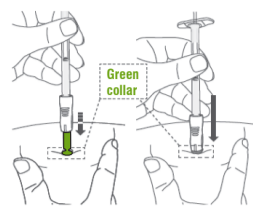


D. Perform injection**D1: Position the syringe**

- 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.

D2: Insert the needle

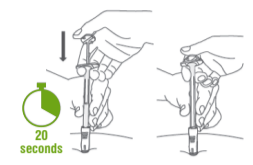
- Without folding or pressing on the skin at the injection site, push the needle firmly against the skin.
- Insert the needle perpendicular to the skin (90-degree angle), all the way into the skin. The **GREEN NEEDLE SHIELD** will retract, and the safety mechanism will activate.
- Continue to insert the needle until only the collar of the GREEN NEEDLE SHIELD is visible.**
- Note: Maintain this position until the injection is completed. Avoid pulling the needle back/outward, 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.



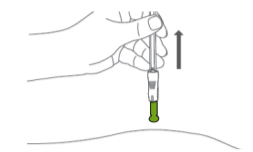
Note: during injection, maintain pressure on the needle to avoid activation of the automatic safety system

D3: Push the top of the plunger

- Release injection site that has been flattened by your hand.
- Move your hand from the skin to the plunger.
- 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.

**E. Remove and throw away syringe****E1: Remove from the skin**

- Lift the syringe straight up and away from your body.
- The **GREEN NEEDLE SHIELD** will cover the needle.

**E2: 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.

**E3: Throw away**

- 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.



If you use more Lanreotide Solution for Injection than you should

If you have injected more Lanreotide Solution for Injection than you should, please tell your doctor. If you have injected or if you are given too much Lanreotide Solution for Injection you may experience additional or more severe side effects (see section 4 "Possible Side Effects").

If you forget to use Lanreotide Solution for Injection

As soon as you realise that you have missed an injection, contact your healthcare professional, who will give you advice about the timing of your next injection. Do not self-inject extra injections to make up for a forgotten injection, without discussing with your healthcare professional.

If you stop using Lanreotide Solution for Injection

An interruption of more than one dose or early termination of the Lanreotide Solution for Injection treatment can affect the success of the treatment. Please talk to your doctor before you stop the treatment. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following side effects:

- Feeling more thirsty or tired than usual, and having a dry mouth. These may be signs that you have high blood sugar levels or are developing diabetes.
- Feeling hungry, shaky, sweating more than usual or feeling confused. These may be signs of low blood sugar levels.

The frequency of these side effects is common, it may affect up to 1 in 10 people.

Tell your doctor immediately if you notice that:

- Your face becomes flushed or swollen or you develop spots or a rash
- Your chest feels tight, you become short of breath or wheezy
- You feel faint, possibly as a result of a drop in blood pressure.

These might be the result of an allergic reaction.

The frequency of these side effects is not known; it cannot be estimated from the available data.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects.

The most commonly expected side effects are gastrointestinal disorders, gallbladder problems and injection site reactions. The side effects that could occur with Lanreotide Solution for Injection are listed according to their frequencies below.

Very common: may affect more than 1 in 10 people:

- Diarrhoea, loose stools, abdominal pain
- Gallstones and other gallbladder problems. You may have symptoms such as severe and sudden abdominal pain, high fever, jaundice (yellowing of the skin and whites of the eyes), chills, loss of appetite, itchy skin.

Common: may affect up to 1 in 10 people:

- Weight loss
- Lack of energy
- Slow heart beat
- Feeling very tired
- Decrease in appetite
- Feeling generally weak
- Excess fat in the stools
- Feeling dizzy, having a headache
- Loss of hair or less development of body hair
- Pain that affects muscles, ligaments, tendons and bones
- Reactions where the injection is given such as pain, hard skin or itching
- Abnormal liver and pancreas test results and changes in blood sugar levels
- Nausea, vomiting, constipation, passing wind, stomach bloating or discomfort, indigestion
- Biliary dilatation (enlargement of the bile ducts between your liver and gallbladder and the intestine). You may have symptoms such as stomach pain, nausea, jaundice and fever

Uncommon: may affect up to 1 in 100 people:

- Hot flushes
- Difficulty sleeping
- A change in the colour of the stools
- Changes to sodium and alkaline phosphatase levels, shown in blood tests.

Not known: frequency cannot be estimated from the available data:

- Sudden, severe pain in your lower stomach. This may be a sign of an inflamed pancreas (pancreatitis)
- Abscess at the site of injection which may feel fluid-filled when pressed (redness, pain, warmth and swelling which may be associated with fever)
- Inflammation of the gallbladder (cholecystitis) - you may have symptoms such as severe and sudden pain in the upper right or centre abdomen, the pain may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever
- Pain in the upper right part of your belly (abdomen), fever, chills, yellowing of the skin and eyes (jaundice), nausea, vomiting, clay-coloured stools, dark urine, tiredness – these may be signs of inflammation of the bile duct (cholangitis).

Since Lanreotide Solution for Injection may alter your blood sugar levels, your doctor may want to monitor your blood sugar levels especially at the initiation of the treatment.

Similarly, as gallbladder problems can occur with this type of medicine, your doctor may want to monitor your gallbladder when you start receiving Lanreotide Solution for Injection, and from time to time afterwards.

Tell your doctor or pharmacist if you notice any of the side effects above.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LANREOTIDE SOLUTION FOR INJECTION

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after [EXP]. The expiry date refers to the last day of that month.

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

Store Lanreotide Solution for Injection in a refrigerator (2°C – 8°C) in the original package in order to protect from light.

Once removed from the refrigerator, product left in its sealed pouch may be returned to the refrigerator (the number of temperature excursions must not exceed three times) for continued storage and later use, provided it has been stored for no longer than a total of 72 hours at a maximum temperature of 40 °C.

Each syringe is packed individually.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lanreotide Solution for Injection contains

- The active substance is lanreotide (60 mg, 90 mg or 120 mg)
- The other ingredients are water for injection and glacial acetic acid (for pH adjustment).

What Lanreotide Solution for Injection looks like and contents of the pack

Lanreotide Solution for Injection is a viscous solution for injection in a 0.5 mL semi-transparent plastic syringe accompanied with a single use needle-safe device. It is a white to pale yellow semisolid formulation.

Each pre-filled syringe is packed in an aluminium pouch and in a carton box.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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ADVANZ PHARMA Limited is part of the ADVANZ PHARMA Group

This leaflet was last revised in 02/2025.

AW-LF-0001224 (v0.9)

AMS Component No.:	AW-LF-0001224 (v0.9)
Product Description:	LANREOTIDE 120MG, 60MG 90MG SOL FOR INJ IN PFS UK
Component:	Leaflet
Product Code:	104055,104056, 104057
Country:	UK
Vendor Name:	Pharmathen S.A.
Proof Number:	0.9
Revision Date:	04-Feb-2025
Revised by:	DAJ

Dimension:	170 x 800 mm
Commodity No.:	N/A
Pharma Code:	N/A
QR Job Code No.:	UK/LAN/NP/0023
Print Colours:	369 C , 485 C & Black
Non-Print Colours:	Cutter
Min. Font Size:	9 pt