

Lanreotide Patient information

What is Lanreotide Solution for Injection is and what it is used for

Lanreotide Solution for Injection contains the active substance lanreotide, which is an “Antigrowth hormone”. It lowers the levels of hormones in the body such as growth hormone (GH), and insulin-like growth factor 1 (IGF-1) and stops the release of some hormones in the digestive tract and intestine.

Lanreotide also has an effect on neuroendocrine tumours of the intestine and pancreas by stopping or delaying their growth.

This product can be prescribed for the following

- Treatment of acromegaly
(*What is acromegaly: a condition where your body produces too much growth hormone.*)
- To relieve symptoms such as flushing and diarrhoea that sometimes occur in patients with neuroendocrine tumours (NETs)
(*What are NETs: Rare tumours that start in neuroendocrine cells. There are a number of different types of NETs. The type you have depends on the type of cell that the cancer started in.*)
- The treatment and control of the growth of some advanced tumours of the intestine and pancreas called ‘gastroenteropancreatic neuroendocrine tumours (GEP-NETs.) It is used when these tumours cannot be removed by surgery.

What you need to know before you use Lanreotide Solution for Injection

In which situations should I not use Lanreotide Solution for Injection?

- if you are allergic to lanreotide, somatostatin or drugs from the same family (analogues of somatostatin)
- If you are allergic to any of the ingredients within this medicine; water for injection, glacial acetic acid

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lanreotide Solution for Injection:

- If you are **diabetic**, as Lanreotide Solution for Injection may affect your blood sugar levels. Your doctor may check your blood sugar levels and possibly alter your anti-diabetic treatment while you are receiving Lanreotide Solution for Injection
- If you have **gallstones**, as Lanreotide Solution for Injection may lead to gallstone formation in the gallbladder. In this case, you may need to be monitored periodically. Your doctor may decide to stop treatment with lanreotide if complications arising from gallstones occur
- If you have any **thyroid problems**, as Lanreotide Solution for Injection may slightly decrease your thyroid function
- If you have **cardiac disorders**, as bradycardia (slower heart beat) may occur under Lanreotide Solution for Injection treatment. Special care should be taken when initiating treatment with Lanreotide Solution for Injection in patients with bradycardia.

If any of the above applies to you, talk to your doctor or pharmacist before using Lanreotide Solution for Injection.

Can Lanreotide Solution for Injection be used in Children ?

Lanreotide Solution for Injection is not recommended in children.

Are there any interactions between other medicines and Lanreotide Solution for Injection?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Special care should be taken in case of co-administration with:

- **Ciclosporin** (a drug reducing immune reactions e.g. after transplantation or in cases of autoimmune disease)
- **Bromocriptine** (dopamine agonist used in the treatment of certain types of tumours of the brain and Parkinson's disease, or to prevent lactation following childbirth)
- **Bradycardia inducing drugs** (drugs slowing the heart beat, e.g beta blockers).

Dose adjustments of such concomitant medications may be considered by your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

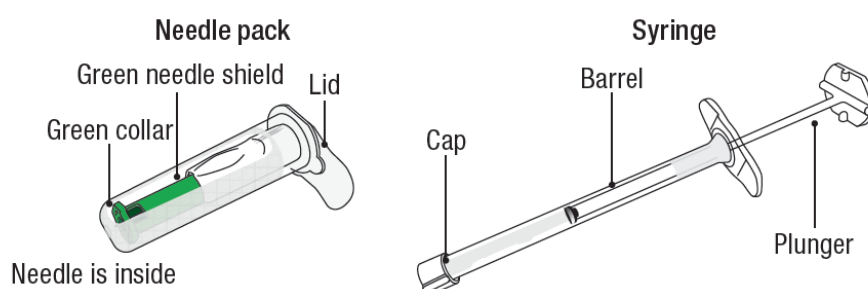
If so, Lanreotide Solution for Injection should be given to you only if clearly needed.

Driving and using machines

Lanreotide Solution for Injection is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with Lanreotide Solution for Injection. If you are affected be careful when driving or using machinery.

What is in the box I have been given?

Lanreotide Solution for Injection contains a semi-transparent plastic syringe accompanied with a single use needle-safe device. Please contact your pharmacy if you have a problem with the box of medicine you have been supplied with; alternatively contact medicalinformation@advanzpharma.com



What does Lanreotide Solution for Injection look like?

Lanreotide Solution for Injection is a viscous, white to pale yellow semi-solid formulation. 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. Please talk to your doctor or pharmacist if you are not sure.

How to use Lanreotide Solution for Injection (SRL005/ patient video)

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

Treatment of acromegaly

The recommended dose is one injection every 28 days. Your doctor may adapt the dose of your injection using one of the three available strengths of Lanreotide Solution for Injection (60, 90 or 120mg).

If you are well controlled on your treatment, your doctor can recommend a change in the frequency of your Lanreotide 120 mg injections to one injection every 42 or 56 days. Any change in dose will depend on your symptoms and how you respond to the medicine.

Your doctor will also decide how long you should be treated for.

Relief of symptoms (such as flushing and diarrhoea) associated with neuroendocrine tumours

The recommended dose is one injection every 28 days. Your doctor may adapt the dose of your injection using one of the three available strengths of Lanreotide Solution for Injection (60, 90 or 120 mg).

If you are well-controlled on your treatment, your doctor can recommend a change in the frequency of

your Lanreotide 120 mg injections to one injection every 42 or 56 days.

Your doctor will also decide how long you should be treated for.

Treatment of advanced tumours of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs. Used when these tumours cannot be removed by surgery.

The recommended dose is 120 mg every 28 days. Your doctor will decide how long you should be treated with Lanreotide Solution for Injection for tumour control.

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 "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.

Method of administration

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.

- 1) Remove lanreotide prefilled syringe from the refrigerator 30 minutes prior to injecting.
- 2) Clean surface for preparation.
- 3) Choose injection site (*where do I inject?*)
 - 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*
- 4) Wash hands and clean the injection site
- 5) Prepare the syringe for injection: (*how do I prepare the syringe?*)
 - a. *remove the cap from the syringe*
 - i. *With one hand, hold the syringe barrel steady (not the plunger).*
 - ii. *With the other hand, remove the cap by twisting it. Open the needle pack*
 - b. *Hold the needle pack and pull the lid off. Do not touch the open end of the needle pack. This needs to stay sterile.*
 - c. *Attach the needle pack to the syringe barrel*
 - i. *Put the end of the syringe into open end of the needle pack*
 - ii. *Hold the needle pack with one hand.*
 - iii. *With the other, hold the syringe barrel steady (not the plunger) and twist until the syringe and needle are fully locked together. Both the needle pack and syringe barrel should be straight when screwing so they are fully locked when you cannot turn it any further. This must be tight to avoid drug leakage.*
 - d. *Remove the needle from the pack*
 - i. *Hold the syringe barrel (not the plunger).*
 - ii. *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
- 6) Perform Injection
 - i. *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.*
 - ii. *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*
 - iii. *Push the top of the plunger*
 - a. *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.*
 - b. *This should take around 20 seconds.*
- 7) Remove and throw away syringe

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 or hard skin
- Abnormal liver and pancreas test results and changes in blood sugar levels
- Nausea, vomiting, constipation, 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 - 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.

Additionally please report your any side effect(s) you experience following administration to medicalinformation@advanzpharma.com.

How to store Lanreotide Solution for Injection

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 24 hours at below 40°C.

How do I dispose of injection?

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 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

Contents of the pack and other information (picture)

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 semi-solid 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).

Allergen Information

- **Is Lanreotide 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?**
 - pH 5.5-6.5
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