Package leaflet: Information for the user

Lanreotide SUN 60 mg solution for injection in a pre-filled syringe
Lanreotide SUN 90 mg solution for injection in a pre-filled syringe
Lanreotide SUN 120 mg solution for injection in a pre-filled syringe
lanreotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor of pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Lanreotide SUN is and what it is used for

What Lanreotide SUN is and how it works
The name of your medicine is Lanreotide SUN.
It is a long acting formulation of lanreotide.

Lanreotide, the active substance, belongs to a group of medicines called ‘antigrowth hormones’. It is similar to another substance (a hormone) called ‘somatostatin’.

Lanreotide lowers the levels of hormones in the body such as growth hormone (GH), and insulin-like growth factor 1 (IGF-1) and inhibits the release of some hormones in the gastrointestinal tract and intestinal secretions. Additionally, it has an effect on some advanced type of tumours (called neuroendocrine tumours) of the intestine and pancreas by stopping or delaying their growth.

What Lanreotide SUN is used for:
- The long term treatment of acromegaly (a condition where your body produces too much growth hormone).
- The relief of symptoms associated with acromegaly – such as feeling tired, headaches, sweating, joint pain and numb hands and feet.
- The relief of symptoms such as flushing and diarrhoea that sometimes occur in patients with neuroendocrine tumours (NETs).
- The treatment and control of the growth of some advanced tumours of the intestine and pancreas, called gastroenteropancreatic neuroendocrine tumours or GEP NETs. It is used when these tumours cannot be removed by surgery.

2. What you need to know before you use Lanreotide SUN

Do not use Lanreotide SUN

- If you are allergic (hypersensitive) to lanreotide, somatostatin or drugs from the same family (analogues of somatostatin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using this medicine:
- If you are **diabetic**, as lanreotide 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.
- If you have **gallstones**, as lanreotide 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 may slightly decrease your thyroid function.
- If you have **cardiac disorders**, as sinus bradycardia (slower heart beat) may occur with lanreotide treatment. Special care should be taken when initiating treatment with lanreotide in patients with bradycardia (heart rhythm disorder).

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

Talk to your doctor or pharmacist during the treatment:
• If you have **fatty stools, loose stools, abdominal bloating or weight loss**, as lanreotide may affect pancreatic enzymes secretion involved in food digestion.

Children and adolescents
Lanreotide SUN is not recommended in children and adolescents.

Other medicines and Lanreotide SUN
Some medicines have an effect on the action of other medicines. 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 reaction taken 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),
- **anti-diabetic treatment** (drug reducing high blood glucose levels)
- **bradycardia inducing drugs** (drugs slowering the heart beat, such as 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 might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Lanreotide SUN should be administered to you only if clearly needed.

Driving and using machines
Lanreotide SUN is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with Lanreotide SUN. If you are affected, you should not drive or use machines.

3. How to use Lanreotide SUN

Always use Lanreotide SUN 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 SUN (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 SUN 120 mg injections to one injection every 42 or 56 days.

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 SUN (60, 90 or 120 mg).

If you are well controlled on a somatostatin analogue or Lanreotide SUN 60 mg or 90 mg, your doctor can recommend a change in the frequency of your Lanreotide SUN 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 SUN for tumour control.

Method of administration
Lanreotide SUN should be administered by deep subcutaneous injection.

The injection should be given by a healthcare professional (HCP) or a caregiver (family member or friend) or yourself after appropriate training from an HCP.

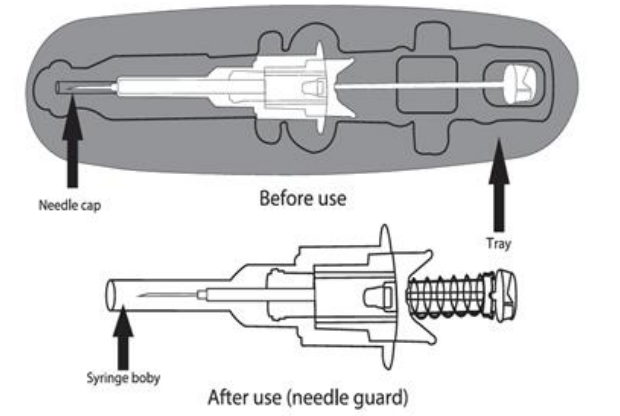
The decision of self-administration or administration by another trained person should be taken by your doctor. If you have any doubt on how to administer this injection at any time please contact your doctor or HCP for advice or further training.

If the injection is being given by a healthcare professional or someone else who has been trained (family member or friend), the injection will be given in the upper, outer external quadrant of the buttock or the upper outer thigh (see figs. 5a & 5b below).

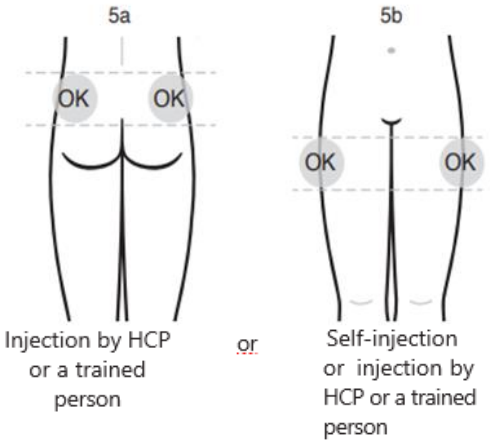
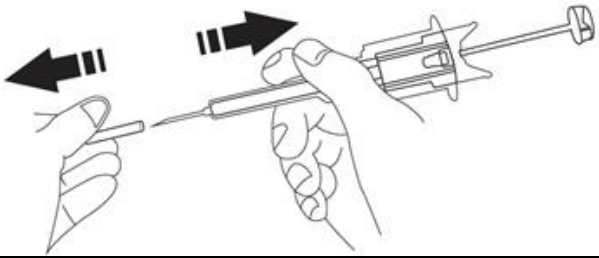
If you are injecting yourself after appropriate training, the injection should be given in the upper outer thigh (see fig. 5b below).

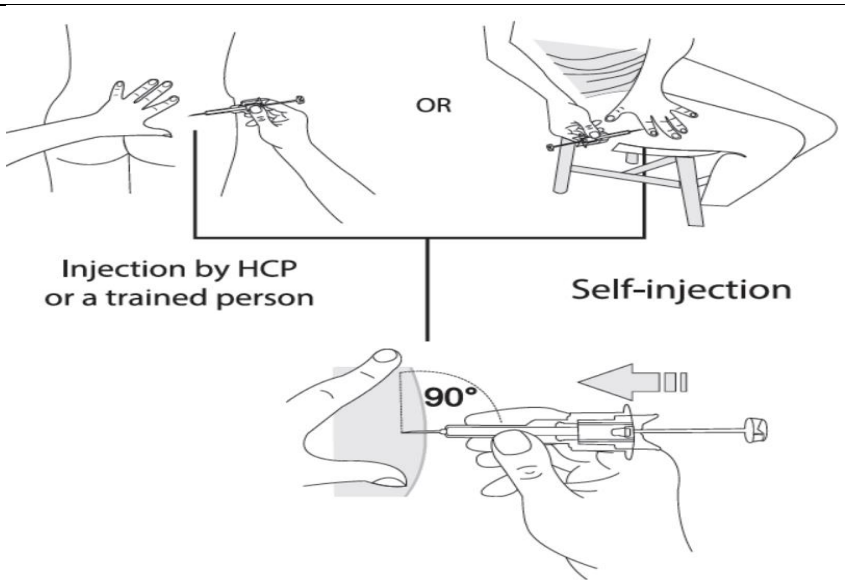
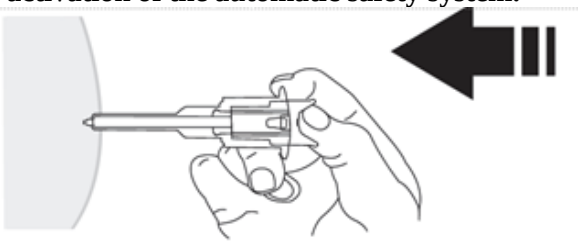
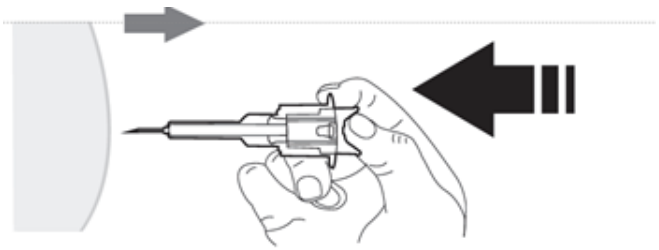
Instructions for Use
Attention: Please read all the instructions carefully before starting the injection. The injection is a deep subcutaneous injection that requires a specific technique different to normal subcutaneous injections.

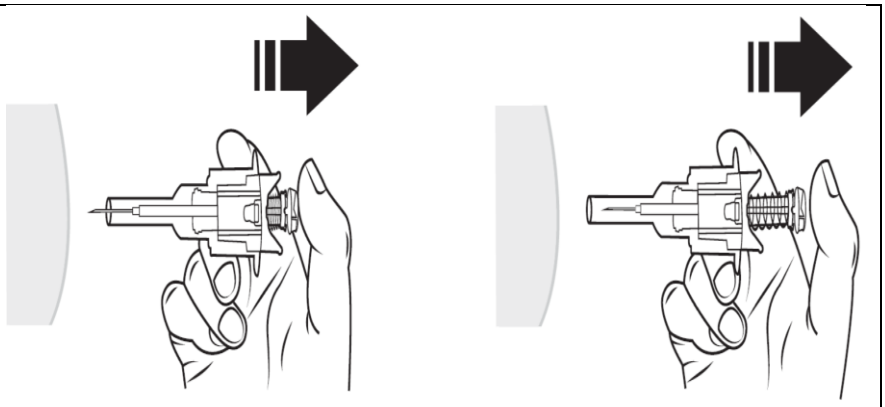
The following instructions explain how to inject Lanreotide SUN.
Lanreotide SUN is supplied in a ready to use pre-filled syringe fitted with an automatic safety system. The needle will retract automatically following the full administration of the product to prevent needle stick injury.



1. Remove Lanreotide SUN from the refrigerator 30 minutes prior to administration. Injection of cold medication may be painful. Keep laminated pouch sealed until just prior to injection.	
2. **Attention Before opening the pouch, check that it is intact and that the medication has not** expired. **<u>Do not use the pre-filled syringe:</u>** • If you drop or damage the pre-filled syringe or if the pre-filled syringe or pouch appear damaged in any way. • If the product has expired; the expiry date is printed on the outer carton and the pouch. If any of the above apply you should contact your doctor or pharmacist.	
3. Wash hands with soap.	
4. Tear-open the pouch along the dotted line and take out the pre-filled syringe. The content of the pre-filled 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.	 After opening the protective laminated pouch, the product should be administered immediately.

5. Select an injection site: 5a. If a healthcare professional (HCP) or someone else like a trained family member or friend is doing the injection: use the superior external (upper, outer) quadrant of the buttock or the upper outer thigh for injection. 5b. If you are injecting yourself: use the upper outer part of your thigh.	 • **Alternate the injection site** between the right and left side each time you receive an injection of Lanreotide SUN. Avoid areas with moles, scar tissue, reddened skin, or skin that feels bumpy.
6. Clean the injection site.	
7. Before injecting, remove the pre-filled syringe from its tray. Discard the tray.	
8. Remove the needle cap by pulling off and discard it.	
9. **Flatten** injection area using the thumb and index finger of the hand not holding the pre-filled syringe to stretch the skin. **Do not pinch** the skin. Use a strong, straight dart-like motion to **quickly insert** the needle **perpendicular** to the skin (90-degree angle), all the way into	

the skin. It is very important that you insert the needle **completely**. You should not see any needle once it is fully inserted.	 **Do not aspirate** (do not draw back)
10. Release injection site that has been flattened by your hand. Push plunger with **steady very firm pressure**. The medication is thicker and harder to push than you might expect.	Typically 20 seconds are needed. Inject the **full dose and give a final push** to make sure you can not depress it any further.  **Note: maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.** 
11. Without releasing the pressure on the plunger, withdraw the needle from the injection site.	

12. Then release pressure on the plunger. The needle will automatically retract into the needle guard where it will be locked permanently.	
13. 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.	
14. Dispose of the used syringe as instructed by your doctor or healthcare provider. **Do not dispose** of the device in your general household rubbish.	

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

If you forget to use Lanreotide SUN
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 SUN
An interruption of more than one dose or early termination of the Lanreotide SUN 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 this side effect 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 SUN 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, 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)
- redness, pain, warmth and swelling at the injection site that may feel fluid-filled when pressed, fever – this may be a sign of abscess
- sudden, severe pain in the upper right or centre abdomen that may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever – this may be a sign of inflammation of the gallbladder (cholecystitis)
- 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)
- Decrease in pancreatic enzymes. As lanreotide may affect the release of pancreatic enzymes involved in food digestion, you may have symptoms such as fatty stools, loose stools, abdominal bloating or weight loss.

Since Lanreotide SUN 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 SUN 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Lanreotide SUN

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

Do not use this medicine after the expiry date which is printed on the carton and labels after <exp>. The expiry date refers to the last day of that month.
Store Lanreotide SUN between 2°C to 8°C in a refrigerator in its 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 below 30°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 no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lanreotide SUN contains
The active substance is:
Each pre-filled syringe contains a supersaturated solution of lanreotide acetate corresponding to 0.246 mg of lanreotide base/mg of solution, which ensures an actual injection dose of 60 mg, 90 mg and 120 mg of lanreotide respectively.

The other ingredients are:
water for injection
glacial acetic acid (for pH adjustment)

What Lanreotide SUN looks like and contents of the pack
Lanreotide SUN is a viscous solution for injection in a pre-filled syringe ready to use, fitted with an automatic safety system. It is a white to pale yellow semi solid formulation.

Each pre-filled syringe is packed in a laminated pouch and a cardboard box.

Pack sizes:

Box of 0.5 mL syringe with an automatic safety system and one needle (1.2 mm x 20 mm).
Box of three pouches, each one containing one 0.5 ml pre-filled syringe and one needle (1.2 mm x 20 mm).

Lanreotide SUN is available in packs containing 1 or 3 pre-filled syringes or as multipacks containing 3 (3 x 1) pre-filled syringes.

Not all pack sizes may be marketed.

The Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132JH Hoofddorp
The Netherlands

Terapia SA
124 Fabricii Street,
400632, Cluj-Napoca,
Romania

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria: Lanreotid SUN 60 mg, 90 mg, 120 mg Injektionslösung in einer Fertigspritze
Belgium: Lanreotide SUN 60 mg, 90 mg, 120 mg oplossing voor injectie in een voorgevulde spuit
Czech Republic: Lanreotid SUN
Denmark: Lanreotid SUN 60 mg, 90 mg, 120 mg injektionsvæske, opløsning i fyldt injektionssprøjte
Finland: Lanreotidi SUN 60 mg, 90 mg, 120 mg Injektioneste, liuos, esitäytetyssä ruiskussa
France: Lanreotide SUN L.P. 60 mg, 90 mg, 120 mg solution injectable à libération prolongée en seringue préremplie
Germany: Lanreotid SUN 60 mg, 90 mg, 120 mg Injektionslösung in einer Fertigspritze (ENR: 7010405, 7010406, 7010407)
Hungary: Lanreotid SUN 60 mg, 90 mg, 120 mg oldatos injekció előretöltött fecskendőben
Ireland: Lanreotide SUN 60 mg, 90 mg, 120 mg solution for injection in a pre-filled syringe
Italy: Lanreotide SUN
The Netherlands: Lanreotide SUN 60 mg, 90 mg, 120 mg oplossing voor injectie in een voorgevulde spuit
Norway: Lanreotid SUN
Poland: Lanreotide Ranbaxy
Romania: Lanreotida Terapia 60 mg, 90 mg, 120 mg soluţie injectabilă în seringă preumplută
Spain: Lanreotid SUN 60 mg, 90 mg, 120 mg injektionsvæske, opløsning i fyldt injektionssprøjte
Sweden: Lanreotid SUN 60 mg, 90 mg, 120 mg injektionsvätska, lösning i förfylld spruta
Slovakia: Lanreotid SUN 60 mg, 90 mg, 120 mg injekčný roztok v naplnenej injekčnej striekačke

This leaflet was approved in 02/2025.