PACKAGE LEALET: INFORMATION FOR THE USER

Somatuline LA 30mg
Powder and solvent for prolonged release suspension for injection
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 or nurse.
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Somatuline LA 30 mg is and what it is used for

Somatuline LA 30 mg is a long acting formulation of lanreotide.

Lanreotide – the active substance – belongs to the group of antigrowth A hormones. It is similar to the naturally occurring hormone called somatostatin.

Lanreotide lowers the levels of hormones in the body such as GH (Growth Hormone) and IGF-1 (Insulin-like Growth Factor-1) and inhibits the release of some gastro-intestinal hormones and intestinal secretions.

Somatuline LA 30 mg is indicated for
- The long-term treatment of acromegaly (a condition where too much Growth Hormone is produced)
- The treatment of symptoms that occur with certain endocrine tumours of the gastrointestinal tract.
- The treatment of primary thyrotropic adenomas (pituitary tumour associated with hyperthyroidism)
- The treatment of post-operative digestive fistulae (abnormal passage in the intestinal tract).

2. What you need to know before you use Somatuline LA 30 mg

Do not use Somatuline LA 30 mg
- If you are allergic (hypersensitive) to lanreotide, somatostatin and drugs from the same family (analogues of somatostatin) or any of the other ingredients of Somatuline LA 30 mg (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Somatuline LA 30 mg:

- 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 Somatuline LA 30 mg
- 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 under lanreotide treatment. Special care should be taken when initiating treatment with lanreotide in patients with bradycardia

If any of the above applies to you, talk to your doctor or pharmacist before using Somatuline LA 30 mg.

Children

Somatuline LA 30 mg is not recommended in children.

Other medicines and Somatuline LA 30 mg

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 case of autoimmune disease)
- **Bromocriptine** (dopamine agonist used in the treatment of tumours of the hypophysis and Parkinson's disease or to prevent lactation following childbirth)
- **Bradycardia inducing drugs** (drugs slowing the heart beat, such as beta blockers).

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor immediately if you are pregnant, or if you think you might be pregnant, or if you are breast-feeding. If so, Somatuline LA 30 mg should be administered to you only if clearly needed.

Driving and using machines

Somatuline LA 30 mg is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with Somatuline LA 30 mg. If you are affected, be careful when driving or using machinery.

Important information about the sodium content of Somatuline LA 30 mg

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say it is essentially ‘sodium-free’.

3. How to use Somatuline LA 30 mg

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

Somatuline LA 30 mg should be administered by healthcare professionals. Your doctor or nurse will prepare and give the injections.

The recommended dose
The recommended starting dose is one injection every 14 days. Your doctor may change the length of time between your injections. This will depend on your symptoms and how you respond to the medicine.

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

If you are treated for digestive fistulae, the usual dose is one injection every 10 days (in this specific case, you should not be given more than 4 injections in total).

Method of administration
Somatuline LA 30 mg is administered intramuscularly into the buttock. The injection is performed by healthcare professionals only.

If you receive more Somatuline LA 30 mg than you should
If you are given too much Somatuline LA 30 mg, you may experience additional or more severe side effects (see section 4: "Possible Side Effects"). Please tell your doctor if you think this is the case.

If you forget to use Somatuline LA 30 mg
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 administer yourself extra injections to make up for a forgotten injection.

In long-term treatment, as you may have with Somatuline LA 30 mg one forgotten dosage will not dramatically affect the success of your therapy.

If you stop using Somatuline LA 30 mg
An interruption or early termination of the Somatuline LA 30 mg treatment can affect the success of the treatment. Please ask your doctor before you stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor, or pharmacist, or nurse.

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

The most commonly expected side effects are gastrointestinal disorders, gall bladder problems and injection site reactions. The side effects that could occur with Somatuline LA 30 mg 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 gall bladder 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 affect muscles, ligaments, tendons and bones
- Site 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 gall bladder 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
- 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)

Since lanreotide 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 Somatuline LA 30 mg and from time to time afterwards.

Tell your doctor or pharmacist or nurse 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 HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Somatuline LA 30 mg

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

Store in a refrigerator (2°C to 8°C) in the original package.

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. Do not freeze.

Do not use Somatuline LA if you notice any signs of deterioration.

Somatuline LA 30 mg is for single use only. Your doctor or nurse will dissolve the powder into the solvent to obtain a suspension which should be used immediately after reconstitution. Any unused suspension should be discarded appropriately.

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 to protect the environment.

6. Contents of the pack and other information

What Somatuline LA 30 mg contains

The active substance is:

Lanreotide (30 mg)

The other ingredients are:

Powder:
Lactide glycolide copolymer
Lactic glycolic copolymer
Mannitol
Carmellose sodium
Polysorbate 80.
Solvent:
Mannitol
Water for injections

What Somatuline LA 30 mg looks like and contents of the pack

Somatuline LA 30 mg is provided as powder and solvent for prolonged release suspension for injection.

The powder is practically white and the presence of air bubbles at the top is normal. It is supplied in a small glass vial (fitted with an elastomer stopper and crimped with an aluminium/plastic cap) together with an ampoule containing 2 ml of solvent and with a sterile set of injection made of 1 empty syringe and 2 needles.
The glass vial is slightly tinted.

After reconstitution the suspension has a milky aspect.

Pack size of 1 vial, 1 ampoule, 1 syringe and 2 needles.
Pack size of 2 vials, 2 ampoules, 2 syringes and 4 needles.
Pack size of 6 vials, 6 ampoules, 6 syringes and 12 needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ipsen Pharmaceuticals Ltd.
Blanchardstown Industrial Park
Blanchardstown
Dublin 15, Ireland.

Manufacturer
Ipsen Pharma Biotech
Parc d'activités du plateau de Signes
Chemin départemental N°402
83870 Signes
France

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DETACH HERE AND GIVE INFORMATION TO THE PATIENT

The following information is intended for medical or healthcare professionals only:

INSTRUCTIONS FOR RECONSTITUTION
Somatuline LA 30 mg
Powder and solvent for prolonged release suspension for injection
Lanreotide

Contents of the pack

Your Somatuline LA 30 mg box contains a package leaflet and elements required for a single intramuscular injection (see "What Lanreotide PR 30 mg looks like and contents of the pack" under section 6).

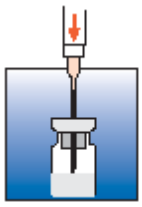
General information
Do not use if the injection set is damaged or opened.

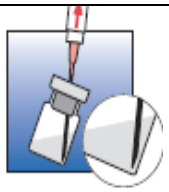
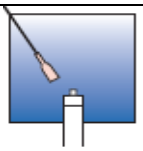
Do not use this product if the expiry date on the box has been passed.

The suspension for injection should be prepared immediately before the injection.

The box with Somatuline LA 30 mg should be removed from the refrigerator 30 minutes before use.

Always use the two needles: one to reconstitute the suspension and to fill the syringe and one to inject the medication into the patient.

1 – PREPARATION OF THE PATIENT		
	The patient should be in a prone position, buttock skin disinfected	
2 – PREPARATION OF THE INJECTION		
	Screw one of the needles onto the syringe (do not remove the needle protection yet!).	
	Break off the ampoule of solvent above the breaking line.	
	Remove the needle protection from the needle and draw up all of the solvent from the ampoule into the syringe.	
	Remove the protection cap from the vial containing the powder. Insert the needle through the rubber stopper of the vial and inject the solvent slowly so that, if possible, it washes down the entire upper part of the vial.	
	Do not remove the syringe from the vial but pull up the needle above the liquid level while reconstituting the homogenous, milky injection suspension by swirling the vial gently between your fingers and **without inverting it**. Caution: mixing must	

	not be performed by repeatedly drawing up and discharging the syringe!	
	Then draw up all of the suspension for injection into the syringe.	
	Remove the first needle from the syringe and remove the air if necessary.	
	Attach the second needle on the syringe and inject the suspension immediately into the patient. Do not mix with other medicinal products.	
3 – INJECTION		
	The injection should be given **intramuscularly** into the gluteal muscle. Inject the contents of the syringe immediately and rapidly. The injection site should be alternated between left and right sides from injection to injection.	
4 – AFTER USE		
	Dispose of the needles and all further material in a designated sharp container. For single use only. Any unused suspension must be discarded.	