SOMATULINE® LA 30 mg

Lanreotide

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully. It provides some information about your medicine. If you have any questions or are not sure about anything after you have read this leaflet, please ask your doctor or pharmacist.

The name of your medicine is Somatuline LA. Its active ingredient is lanreotide. The dose of lanreotide you will receive is 30 mg. There is an extra amount (10 mg) filled into the vial to ensure that the correct dose can be injected. The formulation contains a mixture of copolymers, mannitol, polysorbate 80 and carmellose sodium. For the injection, the Somatuline LA will be made up with the suspension vehicle which contains mannitol in water for injection.

The product is for single use only. Your doctor or nurse will make up the injection and give it to you as described in the instructions.

What is SOMATULINE LA?

Somatuline LA is a prolonged release formulation of lanreotide. Lanreotide is an octapeptide, an analogue of a naturally occurring hormone, somatostatin. Lanreotide lowers the levels of hormones in the body such as GH (growth hormone) and IGF-1 (insulin-like growth factor-1).

What is SOMATULINE LA used for?

Somatuline LA is recommended for the treatment of acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy, or in patients who do not respond to therapy with drugs called dopamine agonists.

Before you are given SOMATULINE LA

When you must not be given it

Do not be given Somatuline LA if

- you are breastfeeding
- you are allergic to lanreotide, the active ingredient of Somatuline LA, or any other somatostatin analogue.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Before you are given it

Tell your doctor if:

- you think you are allergic to any ingredients contained in Somatuline LA.
- you are a diabetic.
- you have ever experienced liver, kidney, thyroid or gallstone problems.
- you are pregnant or think you may be pregnant.

NOTE: Somatuline LA is not recommended for use in children

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription at your pharmacy, supermarket or health food shop.
Some medicines and Somatuline LA may interfere with each other. Somatuline LA may reduce the intestinal absorption of other drugs administered at the same time, (e.g. cyclosporin A) or increase the bioavailability of bromocriptine. The dose of other drugs which reduce the heart rate (e.g. beta-blockers) may need to be reduced if Somatuline LA is administered.

Somatuline LA may interfere with the breakdown of some drugs by the liver enzymes (e.g. quinidine or terfenadine).

Your doctor or pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

How will SOMATULINE LA be given?

Somatuline LA is given by intramuscular injection, usually in your buttock. Initially you will be given one injection every 14 days. Depending on your symptomatic and/or hormonal response to the product, your doctor may vary the frequency of your injections. Your doctor will also decide on the duration of your treatment.

What shall I do if I miss an injection?

As soon as you realise that you have missed an injection, contact your doctor who will then advise when your next injection is to be given.

Side effects

The following side effects have been reported in patients receiving lanreotide injections (as Somatuline Autogel or Somatuline LA).

- bowel problems including diarrhoea or loose stools, abdominal pain, passing wind or constipation
- feeling sick, vomiting, heartburn, abdominal bloating or discomfort
- possible occurrence of gallbladder stones (lithiasis) with long-term treatment
- changes in blood sugar levels (low and high)
- slowing of the heart rate
- tiredness
- headache, dizziness
- hair loss or no hair growth
- moderate and short-lived pain at the injection site, sometimes with redness, swelling (nodule), itching or tenderness
- changes in some blood tests
- weight loss.

If you are a diabetic, your doctor may check your blood sugar levels and possibly alter your anti-diabetic treatment while you are receiving Somatuline LA.

If you have heart problems, your doctor may check your heart rate and possibly alter your treatment while you are receiving Somatuline LA.

Due to the possibility of gallbladder problems with this type of medicine, your doctor may want to conduct a gallbladder scan when you start treatment with Somatuline LA and again at regular intervals thereafter.

If any side effect is troublesome or causes any concern, you should tell your doctor or pharmacist.

What will happen if I am given too much? (Overdose)

As Somatuline LA is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you feel you have been given too much Somatuline LA, contact the Poisons Information Centre on 131126 for advice.

How to store SOMATULINE LA

Store Somatuline LA in the refrigerator, in a safe place out of the reach of children.

DO NOT USE AFTER THE EXPIRY DATE SHOWN ON THE BOX.

Product Description

What it looks like

It is supplied in a pack containing 1 vial of Somatuline LA, 1 ampoule of mannitol diluent, 2 needles and 1 syringe.

Each vial contains a small pellet of white powder which must be mixed with sterile mannitol solution before injection.

Ingredients

Somatuline LA 30mg contains lanreotide 30mg (as acetate) as the active ingredient.

Other ingredients include polyglactin, lactic-glycolic copolymer, mannitol, carmellose sodium, polysorbate 80.

Further Information

If you have any further questions on your Somatuline LA treatment, or are unsure of the information, please see your doctor, who will be able to assist you.

Manufacturer/Supplier

Somatuline LA is manufactured by Ipsen Pharma Biotech, Signes, France.

It is distributed in Australia by:
Ipsen Pty Ltd
Level 2, Building 4
Brandon Office Park
540 Springvale Road
Glen Waverley Victoria 3150

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