

CONSUMER MEDICINE INFORMATION
SOMATULINE[®] LA 30mg

SOMATULINE[®] LA (*lanreotide*)

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.

Is there any reason for not being given Somatuline LA?

Somatuline LA may not be suitable if you have previously been allergic to this drug or any other somatostatin analogues. Somatuline LA is also not suitable for women who are breast feeding. Consult your doctor or pharmacist if you are concerned.

Tell your doctor if:

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

NOTE: Somatuline LA is not recommended for use in children

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 be able to give you your next injection.

Which side effects can Somatuline LA have?

The following side effects have been reported in patients receiving Somatuline LA injections.

- moderate and transitory pain at injection site, sometimes accompanied by a local redness or swelling.
- feeling of weakness, tiredness, headache, dizziness or fever
- diarrhoea or soft stools, abdominal pain or bloating, flatulence, lack of appetite, nausea and vomiting, constipation, anorexia or fatty stools.
- gallbladder problems (lithiasis) in cases of prolonged treatment.
- blood sugar level disturbances.
- changes in liver enzyme tests
- inflammation of the pancreas

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

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

Due to the possibility of gallbladder problems with this medicine, your doctor may want to give you a gallbladder scan when you start taking Somatuline LA and again every six months after that.

What will happen if I am given too much Somatuline LA

If you are given too much Somatuline LA, your doctor will arrange the appropriate care in hospital.

How is Somatuline LA stored?

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.

Pack size

Somatuline LA 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.

Who makes Somatuline LA?

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

It is distributed in Australia by:

Ipsen Pty Ltd

Suite 6, 40 Montclair Avenue

Glen Waverley Victoria 3150

Date of preparation of this leaflet.

October 2005