

CONSUMER MEDICINE INFORMATION
SOMATULINE® AUTOGEL® 60, 90 and 120 mg

SOMATULINE® AUTOGEL® (*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® Autogel®. Somatuline Autogel is a viscous aqueous solution for injection. This solution is packaged in a pre-filled syringe, ready to be injected. The active substance is lanreotide. The dose of lanreotide you will receive is 60, 90 or 120 mg. There is an extra amount filled into the syringe to ensure that the correct dose can be injected. The only other ingredient is sterile water.

The product is for single use only.

What is Somatuline Autogel?

Somatuline Autogel 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 Autogel used for?

Somatuline Autogel is used 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.

Somatuline Autogel is used for the treatment of symptoms associated with certain diseases affecting the intestines.

Is there any reason for not being given Somatuline Autogel?

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

Somatuline Autogel should not be given if you have a tumour blocking your intestines.

Tell your doctor if:

- you are taking any other medicines
- you are a diabetic
- you have ever experienced liver, kidney or gallstone problems
- you have any heart problems
- you are pregnant or think you may be pregnant
- you are breastfeeding.

NOTE: Somatuline Autogel is not recommended for use in children

How will Somatuline Autogel be given?

Somatuline Autogel is intended for deep injection under the skin. It is for single use only. It should be injected as described in the instructions in this leaflet.

The recommended starting dose is 60 mg to 120mg injected every 28 days. Depending on your response to the product, your doctor may vary the dose or the injection frequency. Your doctor will also decide on the length of your treatment.

If you are controlled on Somatuline Autogel, your doctor may decide that the injection can be given by yourself or your carer. Your doctor or nurse will give you or your carer the appropriate training and confirm that you are both motivated and capable of doing this. Your doctor will continue to supervise the long term management of your condition.

If the injection is being administered by a healthcare professional or your carer, the injection will usually be given as a deep subcutaneous injection in the upper, outer external quadrant of the buttock.

If you are giving the injection to yourself, the deep subcutaneous injection should be given in the upper, outer thigh.

The injection site should be alternated between right and left sides.

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.

Which side effects can Somatuline Autogel have?

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

- moderate and short-lived pain at the injection site, sometimes with redness, swelling (nodule) or tenderness. Longer lasting, but temporary reactions may also occur at the injection site
- bowel problems including diarrhoea or loose stools, stomach pain, passing wind , fatty stools
- feeling sick, vomiting, heartburn, loss of appetite
- possible occurrence of gallbladder problems (lithiasis) or increased bilirubin (present in bile) levels with long-term treatment
- changes in blood sugar levels (low and high)
- slowing of the heart rate
- tiredness, headache, dizziness
- allergic skin reactions, hair loss
- inflammation of the pancreas.

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

Due to the possibility of gall bladder problems with this type of medicine, your doctor may want to give you a gall bladder scan when you start receiving Somatuline Autogel 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 Somatuline Autogel

As Somatuline Autogel 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 Autogel, contact the Poisons Information Centre on 131126 for advice.

How is Somatuline Autogel stored?

Store Somatuline Autogel at 2°C – 8°C in a refrigerator in its original package. Do not freeze. Keep it out of the reach and sight of children. Do not use after the expiry date shown on the labels and box.

Pack size

Somatuline Autogel is supplied in a pack containing 1 pre-filled syringe, ready for use.

Who supplies Somatuline Autogel?

Somatuline Autogel is manufactured in France and distributed in Australia by:
Ipsen Pty Ltd
Suite 6, 40 Montclair Ave
Glen Waverley Victoria 3150

AUST R No:

Somatuline Autogel 60mg: 95260
Somatuline Autogel 90mg: 95261
Somatuline Autogel 120mg: 95262

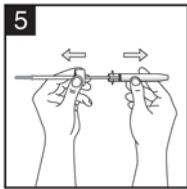
Date of preparation of this leaflet. July 2007

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Instructions for administration of the product

FOLLOW THESE INSTRUCTIONS CAREFULLY.

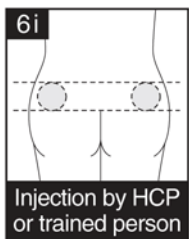
1. Remove Somatuline Autogel from the fridge 30 minutes prior to administration.
2. Wash hands and ensure there is a clear area for preparation.
3. Unless the product is being self-administered, surgical gloves should be worn.
4. Check the laminated pack is intact before opening and take out the pre-filled syringe.
5. Remove the plunger protection.



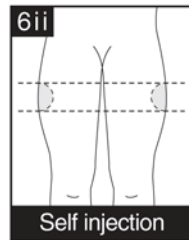
6. If the injection is being administered by a healthcare professional (HCP) or a trained relative/friend of the patient, the injection should be given in the upper, outer quadrant of the buttock (see **figures marked (i)** – Injection by HCP or trained person)

If the injection is being self-administered, the injection should be given in the upper, outer thigh (see **figures marked (ii)** – Self-injection).

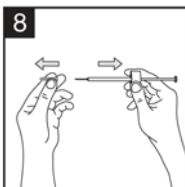
For subsequent injections, the injection site should be alternated between right and left sides.



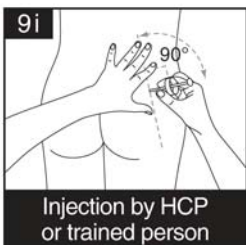
OR



7. Clean the injection site without rubbing the skin excessively.
8. Remove the needle cap.



9. Stretch the skin of the injection site and rapidly insert the needle to its full length, at right angles (90°) to the skin (deep subcutaneous injection).



OR



10. Inject all the drug slowly, using a constant pressure on the plunger and without moving the needle.



OR



11. Press a cotton wool ball against the skin around the needle. Remove the needle and press on the cotton wool for 5 seconds or until any bleeding has stopped, DO NOT rub or massage the injection site after administration.
12. After using, do not attempt to re-sheath the needle but carefully dispose of the used device in the special bin provided. DO NOT dispose of the device in your general household rubbish.
13. Keep the sharps bin and Somatuline Autogel out of reach and sight of children.

DO NOT USE AFTER THE EXPIRY DATE SHOWN ON THE LABELS AND BOX.
DO NOT USE IF THE LAMINATED PACK IS DAMAGED OR OPENED.