SOMATULINE® AUTOGEL®

60, 90 AND 120 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® Autogel®. Somatuline Autogel is a solution for injection in a pre-filled syringe, ready to use and fitted with an automatic safety system. It is a white to pale yellow semi-solid formulation. 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 other ingredients are sterile water and acetic acid.

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 carcinoid syndrome, such as flushing and diarrhoea.

Somatuline Autogel is used for the treatment and control of the growth of some advanced tumours of the intestine and pancreas that cannot be removed by surgery (called gastroenteropancreatic neuroendocrine tumours or GEP-NETs).

Before you are given SOMATULINE AUTOGEL

When you must not be given it

Do not be given Somatuline Autogel if:

- you are breastfeeding
- you have a tumour blocking your intestines
- you are allergic to lanreotide, the active ingredient of Somatuline Autogel.

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 are a diabetic
- you have ever experienced liver, kidney, thyroid or gallstone problems
- you have any heart problems, as sinus bradycardia (slow heart rate) may occur during Somatuline Autogel treatment. Special care should be taken when initiating Somatuline Autogel treatment in patients with bradycardia.
- you are pregnant or think you may be pregnant
- you are breastfeeding.

Somatuline Autogel 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 Autogel may interfere with each

other. Somatuline Autogel 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 Autogel is administered.

Somatuline Autogel 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 taking this medicine.

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.

For the treatment of acromegaly or the symptoms of carcinoid syndrome, the recommended starting dose is 60 mg to 120 mg 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 for the treatment of acromegaly or the symptoms of carcinoid syndrome, your doctor may suggest 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.

For the treatment of advanced tumours of the intestine and pancreas that cannot be removed by surgery (gastroenteropancreatic neuroendocrine tumours - GEP-NETs), the recommended dose is 120mg every 28 days. Your doctor will decide how long you should be treated with Somatuline Autogel for tumour control.

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 as common or very common in patients receiving Somatuline Autogel injections:

- 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. 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.
- changes in blood sugar levels (low and high), diabetes
- 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 liver or pancreas test results
- weight loss
- lack of energy
- feeling generally weak
- decrease in appetite
- pain that affects muscles, ligaments, tendons and bones
- excess fat in the stools
- 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.

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.

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

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

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.

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 these side effects is not known; it cannot be estimated from the available data.

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 Autogel is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Somatuline Autogel comes in a syringe pre-filled with the dose your doctor has prescribed. However, if you feel you have been given too much Somatuline Autogel, contact the Poisons Information Centre on 131126 for advice.

How to store SOMATULINE AUTOGEL

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.

DO NOT USE IF THE LAMINATED POUCH IS DAMAGED OR OPENED.

Product Description

What it looks like

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

Each box contains one 0.5 mL syringe with an automatic safety system and one needle (1.2 mm x 20 mm).

Ingredients

Somatuline Autogel 60 mg contains lanreotide acetate 60 mg as the active ingredient.

Somatuline Autogel 90 mg contains lanreotide acetate 90 mg as the active ingredient.

Somatuline Autogel 120 mg contains lanreotide acetate 120 mg as the active ingredient.

The other ingredients are sterile water and acetic acid.

Further information

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

Manufacturer/Supplier

Somatuline Autogel is manufactured in France 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

Australian Registration Number (AUST R):

Somatuline Autogel 60 mg: 95260

Somatuline Autogel 90 mg: 95261

Somatuline Autogel 120 mg: 95262

Date of preparation of this leaflet:

July 2015

Ipsen Pty Ltd ABN 47095036909

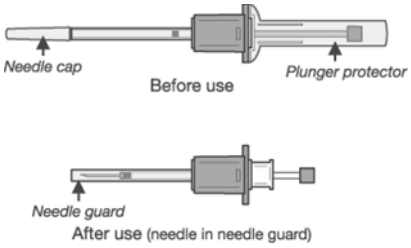
Somatuline® Autogel® is a registered trademark of Ipsen Pty Ltd

Instructions for administration of the product

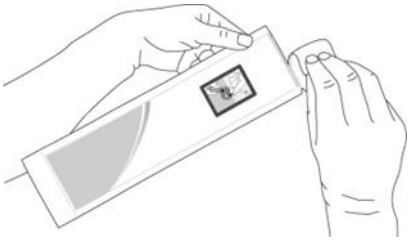
The following instructions explain how to inject Somatuline Autogel.

PLEASE READ ALL THE INSTRUCTIONS CAREFULLY BEFORE STARTING THE INJECTION.

Somatuline Autogel is supplied in a ready to use pre-filled syringe fitted with an automatic safety system that automatically locks in place following administration of the product, to help prevent needle stick injury after use.



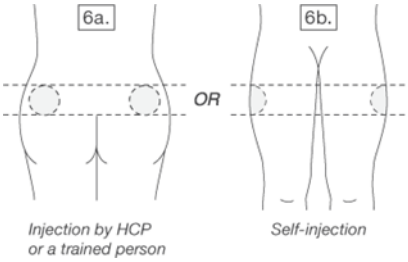
1. Ensure that the medication has been refrigerated in its original package.
2. Remove Somatuline Autogel from the refrigerator 30 minutes prior to administration. Keep pouch sealed until just prior to injection.
3. Before opening the pouch, check that it is intact and that the medication has not expired. The expiration date is printed on the outer carton and the pouch. DO NOT USE IF THE MEDICATION HAS EXPIRED OR IF THE LAMINATED POUCH IS DAMAGED IN ANY WAY.
4. Wash hands with soap and ensure there is a clean area for preparation.
5. Tear open the pouch and take out the pre-filled syringe.



6. Select an injection site:

6a. the superior external quadrant of the buttock (for injection by healthcare professional (HCP) or carer like a trained family member or friend), or

6b. the upper outer part of your thigh (if you will be injecting yourself).

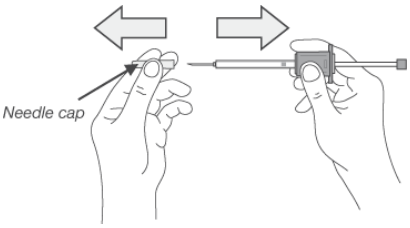


– **Alternate the injection site**

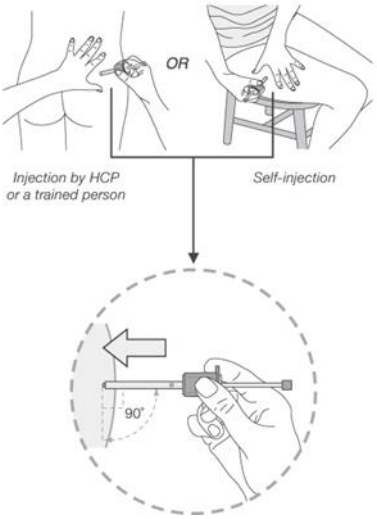
between the right and left side each time you receive an injection of Somatuline Autogel.

7. Clean the injection site without rubbing the skin excessively and let it dry.
8. Twist and pull off the plunger protector and discard it.

9. Remove the needle cap and discard it.



10. Stretch and hold the skin around the injection site flat using your thumb and index finger. Without folding or pressing on the skin at the injection site, rapidly insert the needle to its full length (deep subcutaneous injection), perpendicular (90°) to the skin.

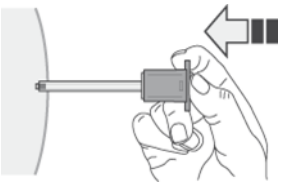


11. Inject the drug SLOWLY

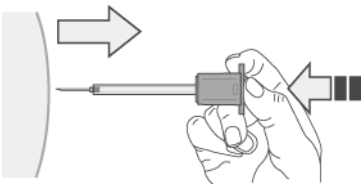
Typically 20 seconds are needed.

Inject the full dose until the plunger cannot be depressed any further. At this point, you will hear a "click".

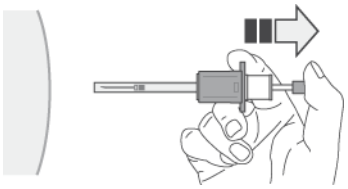
Note: maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.



12. Without releasing the pressure on the plunger, withdraw the needle from the injection site.



13. Then release pressure on the plunger. The needle will automatically retract into the needle guard where it will be locked permanently.



14. 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.
15. Dispose of the used syringe in the syringe disposal container as instructed by your doctor or healthcare provider. DO NOT dispose of the device in your general household rubbish.

    Keep the disposal container and Somatuline Autogel out of reach and sight of children.