

# SOMATULINE AUTOGEL® PROLONGED-RELEASE SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE

Lanreotide acetate (60mg, 90mg, 120mg)

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## What Somatuline Autogel is used for

Somatuline® Autogel® 60 mg/90mg/120mg

Somatuline Autogel is used to treat acromegaly (a condition where too much growth hormone is produced), when the circulating levels of growth hormone and growth factor remain abnormal after surgery and/or radiotherapy and the associated clinical symptoms of acromegaly. It is also used to treat symptoms caused by the abnormal growth of a type of nerve cell (tumour of the neuroendocrine system) such as flushing and diarrhea. Neuroendocrine tumours cause the over production of certain other hormones.

Somatuline® Autogel® 120 mg

The treatment of gastroenteropancreatic neuroendocrine tumours (GEP-NETs) of midgut, pancreatic or unknown origin where hindgut sites of origin have been excluded, in adult patients where cancer or other disease spread from one organ or part to another not directly connect with it.

## How Somatuline Autogel works

Somatuline Autogel is a long acting formulation of lanreotide. Lanreotide is similar to a naturally occurring hormone, somatostatin. Lanreotide lowers the levels of hormones in the body that cause growth. It also lowers the level of other hormones produced

in your stomach and intestines. Additionally, it has an effect on some advanced type of tumours by stopping or delaying their growth.

## Before you use Somatuline Autogel

### - When you must not use it

If you have ever been allergic to lanreotide or any other medicine similar to somatostatin, do not use Somatuline Autogel. Consult your doctor or pharmacist if you are concerned.

### - Before you start to use it

## Tell your doctor if you have or have had any of the following medical conditions:

- you are diabetic
- you have ever experienced thyroid or gallstone problem
- having blockage in the bowel caused by tumour
- presence of excess fat in feces
- you have any heart problems
- you are pregnant or think you may be pregnant you are breastfeeding

### Pregnancy and Breast Feeding

If you are pregnant or breast feeding, ask your doctor or pharmacist for advice before taking any medicine.

### Use in Children

Somatuline Autogel is not recommended in children and adolescents

### Driving and Using Machines

Somatuline Autogel may make you feel dizzy and affect your ability to drive or use machines

### - Taking other medicines

If you are taking cyclosporin as well as Somatuline Autogel, your doctor may want to monitor the amount of cyclosporin in your blood.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines such as:

- diabetic medication ( insulin, glitazones, repaglinide, sulphonylureas)
- medicine to control blood pressure (beta blocker) and medicine to control heart beat (quinidine)
- medicines obtained without a prescription.

## How to use Somatuline Autogel

### - How much to use

Your doctor may change the dose of your injections (between 60 and 120 mg).

### Gastroenteropancreatic Neuroendocrine Tumors.

The recommended dose of SOMATULINE AUTOGEL is 120mg administered every 4 weeks by deep subcutaneous injection. There is no recommended dose adjustment for mild or moderate kidney impairment. There is insufficient information to recommend a dose for individual with severe kidney impairment of any severity.

### - When to use it

Your doctor may change the dose of your injections (between 60 and 120 mg). For individual with Acromegaly, who are well controlled on their treatment the doctor may increase the length of time between injections of the 120mg Autogel to a maximum of 56 days.

### - How long to use it

You will normally be given one injection every 28 days. Continue taking the medicine for as long as your doctor recommends.

### - If you forget to use it

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

- If you use too much (overdose)

If you are given too much Somatuline Autogel you may experience additional or more severe side effects.

If you are not sure what to do, contact your doctor, pharmacist or nurse.

**While you are taking Somatuline Autogel**

- Things you must do

Instructions for administration of Somatuline Autogel, follow these instructions carefully.

1. Remove Somatuline Autogel from the fridge 30 minutes prior to administration. Keep pouch sealed until just prior to injection.
2. Before opening the pouch, check that it is intact and the medication has not expired.
3. Wash hands and ensure there is a clear area for preparation. Unless the product is being self-administered, surgical gloves should be worn.
4. Tear open the pouch and take out the ore filled syringe.

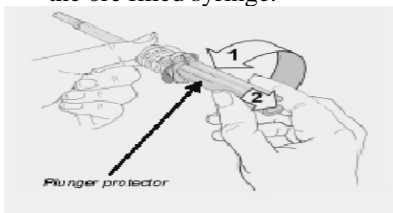
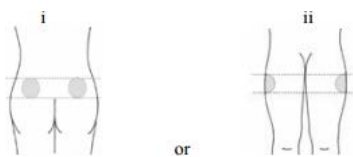
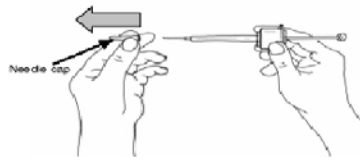


Figure 1: Injections by HCP or trained person

If the injection is being administered by a healthcare professional (HCP) or a trained relative/friend of the individual, the injection should be given in the upper, quadrant of the buttock (see figures marked i- Injections 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.



1. Twist and pull off the plunger protector and discard it.
2. Remove the needle cap.



3. 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, at right angles (90°) to the skin (deep subcutaneous injection).
4. Inject the medicine **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”.

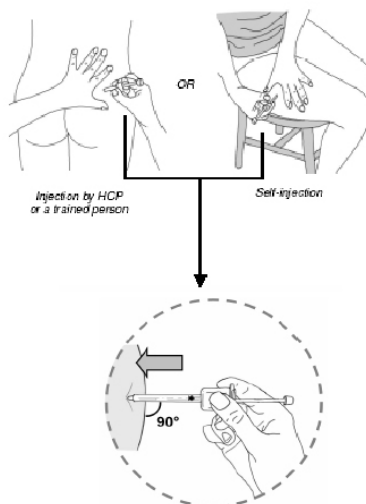


Figure 2: Injection by HCP or trained person OR Self Injection

1. Without releasing the pressure on the plunger, withdraw the needle from the injection side.
2. Then release pressure on the plunger. The needle will automatically retract into the needle guard where it will be locked permanently.
3. Apply gentle pressure to the injection site with a cotton wool to prevent any bleeding.
4. Dispose the used syringe as instructed by your doctor.

- Things you must not do

- **Do not rub or massage** the injection site after the injection.
- **Do not dispose** the device in your general household rubbish.

- Things to be careful of

- Do not use after the expiry date shown on the labels and box.
- Do not use if the laminated pack is damaged or opened.
- Regardless of the site of injection, the skin should not be folded and the needle should be inserted rapidly to its full length, perpendicularly to the skin

**Side effects**

The following side effects have been reported as common or very common in individual receiving Somatuline Autogel injections:

- Diarrhoea
- Stomach ache
- Feeling sick, vomiting
- Gallstones and gall bladder problems
- Constipation
- Flatulence
- Increased bilirubin
- Tiredness
- Headache, dizziness
- Pain at the injection site
- Itching
- Changes in blood sugar levels (low)
- Hearts problem

The following side effects have been reported as rare:

- Inflammation of the pancreas (pancreatitis)

If any of the side effects become serious or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

**Storage and Disposal of Somatuline Autogel**

- Storage

Store Somatuline Autogel at 2°C-8°C in a refrigerator in its original package. Keep it out of the reach and sight of children..

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- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Date of revision**

- 27/04/2016

**Serial Number**

BPFK(R4/1)260416/00124

**Product description**

- What it looks like

Somatuline Autogel is a white to pale yellow semisolid formulation. This solution is packaged in a pre-filled syringe, ready to be injected. Somatuline Autogel is available in three strengths of 60 mg, 90 mg, and 120 mg lanreotide.

- Ingredients

- Active 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

- Inactive ingredients

The only other ingredient is water for injection and acetic acid for pH adjustment

- MAL number:

Somatuline Autogel 60mg

- MAL12085052AZ

Somatuline Autogel 90mg

- MAL12085053AZ

Somatuline Autogel 120mg

- MAL12085051AZ

**Manufacturer**

Ipsen Pharma Biotech  
Chemin Departmental No.402 – 83870  
Signes – France

**Product Registration Holder:**

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