

PACKAGE LEAFLET: INFORMATION FOR THE USER

Somatuline® autogel® 60 mg, solution for injection in a prefilled syringe.

Somatuline® autogel® 90 mg, solution for injection in a prefilled syringe.

Somatuline® autogel® 120 mg, solution for injection in a prefilled syringe.

Lanreotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms and signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Somatuline Autogel is and what it is used for
2. What you need to know before you use Somatuline Autogel
3. How to use Somatuline Autogel
4. Possible side effects
5. How to store Somatuline Autogel
6. Contents of the pack and other information

1. WHAT SOMATULINE AUTOGEL IS AND WHAT IT IS USED FOR

What Somatuline Autogel is and how it works

The name of your medicine is Somatuline Autogel.
It is a long acting formulation of Somatuline.

Lanreotide, the active substance, belongs to a group of medicines called “Antigrowth hormones”. It is similar to another substance (a hormone) called “somatostatin”.

Lanreotide lowers the levels of hormones in the body such as growth hormone (GH), and insulin-like growth factor 1 (IGF-1) and inhibits the release of some hormones in the gastrointestinal tract and intestinal secretions. Additionally, it has an effect on some advanced type of tumours (called neuroendocrine tumours) of the intestine and pancreas by stopping or delaying their growth.

What Somatuline Autogel is used for:

- The treatment of acromegaly (a condition where your body produces too much growth hormone)
- The relief of symptoms such as flushing and diarrhoea that sometimes occur in patients with neuroendocrine tumours (NETs)
- The treatment and control of the growth of some advanced tumours of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs. It is used when these tumours cannot be removed by surgery.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SOMATULINE AUTOGEL

Do not use Somatuline Autogel

- If you are allergic (hypersensitive) to lanreotide, somatostatin or drugs from the same family (analogues of somatostatin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you are **diabetic**, as Somatuline Autogel may affect your blood sugar levels. Your doctor may check your blood sugar levels and possibly alter your anti-diabetic treatment while you are receiving Somatuline Autogel
- If you have **gallstones**, as Somatuline Autogel may lead to gallstone formation. Therefore, you may need to be monitored periodically
- If you have any **thyroid problems**, as Somatuline Autogel may slightly decrease your thyroid function
- If you have **cardiac disorders**, as sinus bradycardia (slower heart beat) may occur under Somatuline Autogel treatment. Special care should be taken when initiating treatment with Somatuline Autogel in patients with bradycardia.

If any of the above applies to you, talk to your doctor or pharmacist before using Somatuline Autogel.

Children

Somatuline Autogel is not recommended in children.

Other medicines and Somatuline Autogel

Some medicines have an effect on the action of other medicines. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Special care should be taken in case of co-administration with:

- **Ciclosporin** (a drug reducing immune reactions e.g. after transplantation or in cases of autoimmune disease)
- **Bromocriptine** (dopamine agonist used in the treatment of certain types of tumours of the brain and Parkinson's disease, or to prevent lactation following childbirth)
- **Bradycardia inducing drugs** (drugs slowing the heart beat, e.g beta blockers).

Dose adjustments of such concomitant medications may be considered by your doctor.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor immediately if you are pregnant, think you might be pregnant or if you are breast-feeding. If so, Somatuline Autogel should be given to you only if clearly needed.

Driving and using machines

Somatuline Autogel is unlikely to affect your ability to drive or use machines, however possible side effects such as dizziness may occur with Somatuline Autogel. If you are affected be careful when driving or using machinery.

3. HOW TO USE SOMATULINE AUTOGEL

Always use Somatuline Autogel exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Recommended dose

Treatment of acromegaly

The recommended dose is one injection every 28 days. Your doctor may adapt the dose of your injection using one of the three available strengths of Somatuline Autogel (60, 90 or 120mg).

If you are well controlled on your treatment, your doctor can recommend a change in the frequency of your Somatuline Autogel 120 mg injections to one injection every 42 or 56 days. Any change in dose will depend on your symptoms and how you respond to the medicine.

Your doctor will also decide how long you should be treated for.

Relief of symptoms (such as flushing and diarrhoea) associated with neuroendocrine tumours

The recommended dose is one injection every 28 days. Your doctor may adapt the dose of your injection using one of the three available strengths of Somatuline Autogel (60, 90 or 120 mg).

If you are well-controlled on your treatment, your doctor can recommend a change in the frequency of your Somatuline Autogel 120 mg injections to one injection every 42 or 56 days.

Your doctor will also decide how long you should be treated for.

Treatment of advanced tumours of the intestine and pancreas called gastroenteropancreatic neuroendocrine tumours or GEP-NETs. Used when these tumours cannot be removed by surgery.

The recommended dose is 120 mg every 28 days. Your doctor will decide how long you should be treated with Somatuline Autogel for tumour control.

Method of administration

Somatuline Autogel should be administered by deep subcutaneous injection.

If the injection is being given by a healthcare professional or someone else who has been trained (family member or friend), the injection will be given in the upper, outer external quadrant of the buttock (see figure 5a below).

If you are injecting yourself after appropriate training, the injection should be given in the upper outer thigh (see figure 5b below).

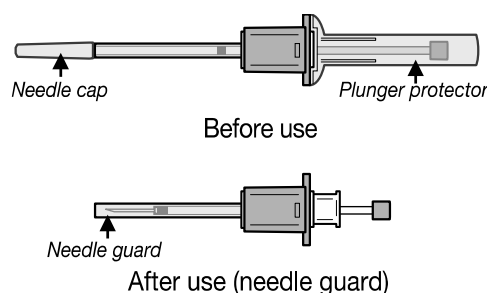
The decision regarding self-administration or administration by another trained person should be taken by your doctor.

Instructions for Use

The following instructions explain how to inject Somatuline Autogel.

PLEASE READ ALL THE INSTRUCTIONS CAREFULLY BEFORE STARTING THE INJECTION.

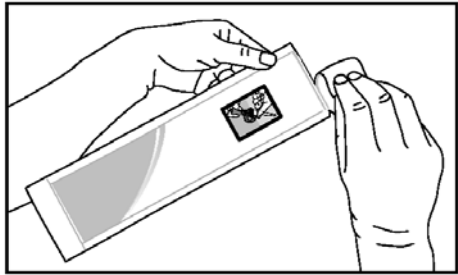
Somatuline Autogel is supplied in a ready to use pre-filled syringe fitted with an automatic safety system that automatically locks in place following the administration of the product to help prevent needle stick injury after use.



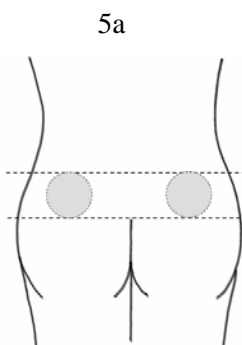
1. Remove Somatuline Autogel from the refrigerator 30 minutes prior to administration. Keep the laminated pouch sealed until just prior to injection.
2. Before opening the pouch, check that it is intact and that the medication has not expired. The expiry date is printed on the outer carton and the pouch.

DO NOT USE IF THE MEDICATION HAS EXPIRED OR IF THE LAMINATED POUCH IS DAMAGED IN ANY WAY.

3. Wash hands with soap and ensure there is a clean area for preparation.
4. Tear open the pouch and take out the pre-filled syringe.

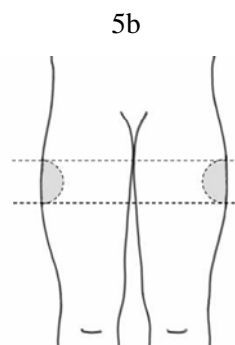


5. Select an injection site:
 - 5a. The superior external (upper, outer) quadrant of the buttock (for injection by healthcare professional (HCP) or someone else like a trained family member or friend)or
 - 5b. The upper outer part of your thigh (if you will be injecting yourself).



Injection by HCP or a trained person

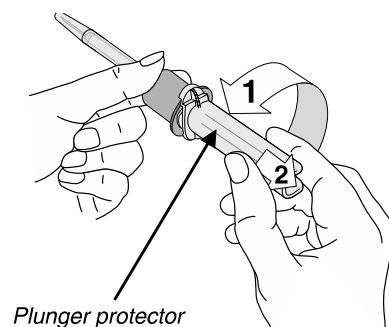
or



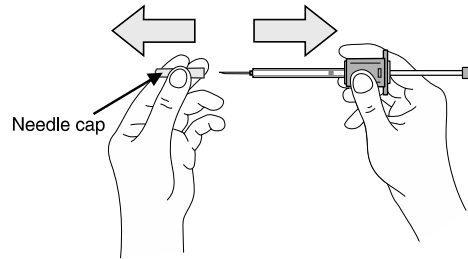
Self-injection

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

6. Clean the injection site.
7. Twist and pull off the plunger protector and discard it.

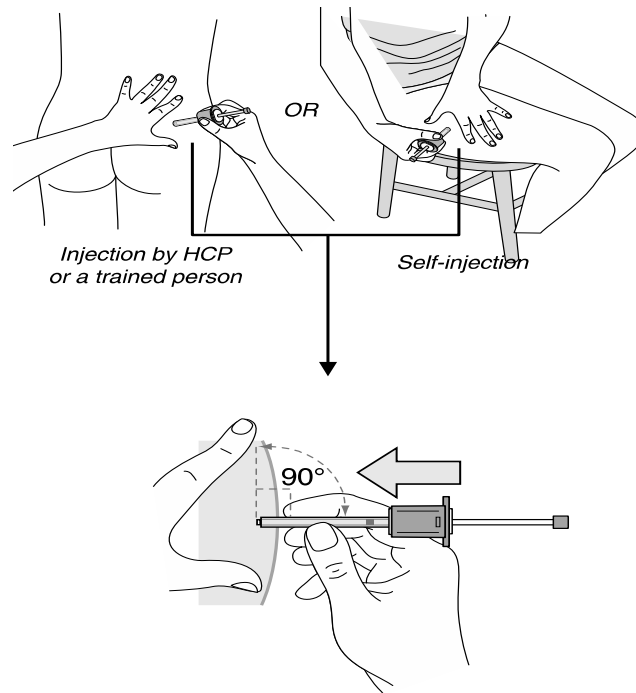


8. Remove the needle cap and discard it.



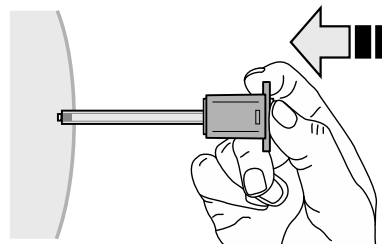
9. Hold the skin around the injection site flat using your thumb and index finger.

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.

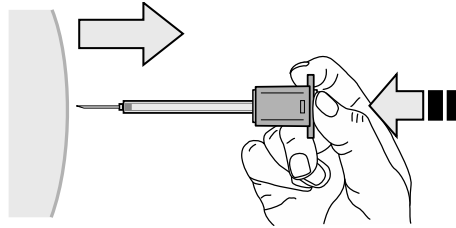


10. Inject the drug **slowly**. Typically, **20 seconds are needed**. Inject the full dose until the plunger cannot be depressed any further. At this point, you will hear a “click”.

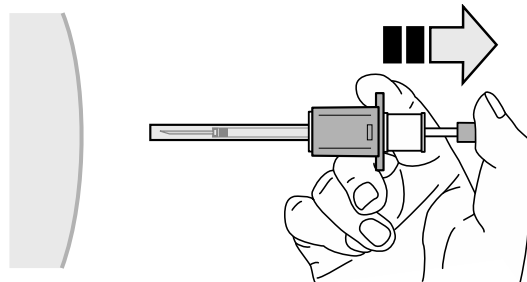
Note: maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.



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



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



13. 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.

14. Dispose of the used syringe as instructed by your doctor or healthcare provider.

DO NOT dispose of the device in your general household rubbish.

If you use more Somatuline Autogel than you should

If you have injected more Somatuline Autogel than you should, please tell your doctor.

If you have injected or if you are given too much Somatuline Autogel you may experience additional or more severe side effects (see section 4 “Possible Side Effects”).

If you forget to use Somatuline Autogel

As soon as you realise that you have missed an injection, contact your healthcare professional, who will give you advice about the timing of your next injection. Do not self-inject extra injections to make up for a forgotten injection, without discussing with your healthcare professional.

If you stop using Somatuline Autogel

An interruption of more than one dose or early termination of the Somatuline Autogel treatment can affect the success of the treatment. Please talk to your doctor before you stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

The frequency of these side effects is common, it may affect up to 1 in 10 people.

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.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects.

The most commonly expected side effects are gastrointestinal disorders, gallbladder problems and injection site reactions. The side effects that could occur with Somatuline Autogel are listed according to their frequencies below.

Very common: may affect more than 1 in 10 people:

- Diarrhoea, loose stools, abdominal pain
- Gallstones and other gallbladder problems. 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.

Common: may affect up to 1 in 10 people:

- Weight loss
- Lack of energy
- Slow heart beat
- Feeling very tired
- Decrease in appetite
- Feeling generally weak
- Excess fat in the stools
- Feeling dizzy, having a headache
- Loss of hair or less development of body hair
- Pain that affects muscles, ligaments, tendons and bones
- Reactions where the injection is given such as pain, hard skin or itching
- Abnormal liver and pancreas test results and changes in blood sugar levels
- Nausea, vomiting, constipation, wind, stomach bloating or discomfort, indigestion
- Biliary dilatation (enlargement of the bile ducts between your liver and gallbladder and the intestine). You may have symptoms such as stomach pain, nausea, jaundice and fever

Uncommon: may affect up to 1 in 100 people:

- Hot flushes
- Difficulty sleeping
- A change in the colour of the stools
- Changes to sodium and alkaline phosphatase levels, shown in blood tests

Not known: frequency cannot be estimated from the available data:

- Sudden, severe pain in your lower stomach. This may be a sign of an inflamed pancreas (pancreatitis).
- Abscess at the site of injection which may feel fluid-filled when pressed (redness, pain, warmth and swelling which may be associated with fever)
- Inflammation of the gallbladder - you may have symptoms such as severe and sudden pain in the upper right or centre abdomen, the pain may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever

Since Somatuline Autogel may alter your blood sugar levels, your doctor may want to monitor your blood sugar levels especially at the initiation of the treatment.

Similarly, as gallbladder problems can occur with this type of medicine, your doctor may want to monitor your gallbladder when you start receiving Somatuline Autogel, and from time to time afterwards.

Tell your doctor or pharmacist if you notice any of the side effects above.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOMATULINE AUTOGEL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is printed on the carton and labels after <exp>. The expiry date refers to the last day of that month.

Store Somatuline Autogel between 2°C to 8°C in a refrigerator in the original package.

Once removed from the refrigerator, product left in its sealed pouch may be returned to the refrigerator for continued storage and later use, provided it has been stored for no longer than 24 hours at below 40°C and the number of temperature excursions does not exceed three.

Each syringe is packed individually.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Somatuline Autogel contains

The active substance is:

Lanreotide (60mg, 90mg or 120mg).

The other ingredients are:

Water for injections

Glacial acetic acid (for pH adjustment)

What Somatuline Autogel looks like and contents of the pack

Somatuline Autogel is a viscous solution for injection in a pre-filled syringe ready to use, fitted with an automatic safety system. It is a white to pale yellow semi-solid formulation

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

Box of 0.5 mL syringe with an automatic safety system and one needle (1.2 mm x 20 mm).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Ipsen Limited

190 Bath Road

Slough

Berkshire SL1 3XE, UK.

Manufacturer:

Ipsen Pharma Biotech

Parc d'activités du plateau de Signes

Chemin départemental N°402

83870 Signes

France.

Is this leaflet hard to see or read? Please phone 01753 627777 and ask for help.

This leaflet was last revised in September 2018.