

Package leaflet: Information for the user

Somatuline® Autogel 120 mg, solution for injection in a pre-filled 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 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.

What is 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 long term treatment of acromegaly (a condition where your body produces too much growth hormone)
- The relief of symptoms associated with acromegaly such as feeling tired, headaches, sweating, joint pain and numb hands and feet
- 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
- If you have **gallstones**, as Somatuline Autogel may lead to gallstone formation in the gallbladder. In this case, you may need to be monitored periodically. Your doctor may decide to stop treatment with lanreotide if complications arising from gallstones occur.
- 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 with 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.

Talk to your doctor or pharmacist during the treatment:

- If you have **fatty stools, loose stools, abdominal bloating or weight loss**, as lanreotide may affect pancreatic enzymes secretion involved in food digestion.

Children and adolescents

Somatuline Autogel is not recommended in children and adolescents.

Other medicines and Somatuline Autogel

Some medicines have an effect on the action of other medicines. 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 taken after transplantation or in cases of autoimmune disease)
- **Bromocriptine** (dopamine agonist used in the treatment of certain types tumours of the brain and Parkinson's disease or to prevent lactation following childbirth)
- **Insulin or any other anti diabetic treatment** (drug reducing high blood glucose levels)
- **Bradycardia inducing drugs** (drugs slowing the heart beat, such as beta blockers).

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. 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 and relief of symptoms 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 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.

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.

The injection should be given by a healthcare professional (HCP) or a caregiver (family member or friend) or yourself after appropriate training from an HCP.

The decision of self-administration or administration by another trained person should be taken by your doctor. If you have any doubt on how to administer this injection at any time, please contact your doctor or HCP for advice or further training.

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 or the upper outer thigh (see figures 5a & 5b below).

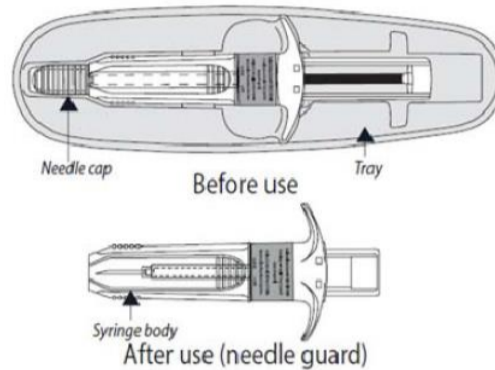
If you are injecting yourself after appropriate training, the injection should be given in the upper outer thigh (see figure 5b below).

Instructions for use

Attention: Please read all the instructions carefully before starting the injection. The injection is a deep subcutaneous injection that requires a specific technique different to normal subcutaneous injections.

The following instructions explain how to inject Somatuline Autogel.

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



1. **Remove Somatuline Autogel from the refrigerator 30 minutes prior to administration.** Injection of cold medication may be painful. Keep the laminated pouch **sealed** until just prior to injection.



2. **Attention:** Before opening the pouch, check that it is intact and that the medication has not expired. **Do not use the pre-filled syringe:**
 - If you drop or damage the pre-filled syringe or if the pre-filled syringe or pouch appear damaged in any way.
 - If the product has expired; the expiry date is printed on the outer carton and the pouch.

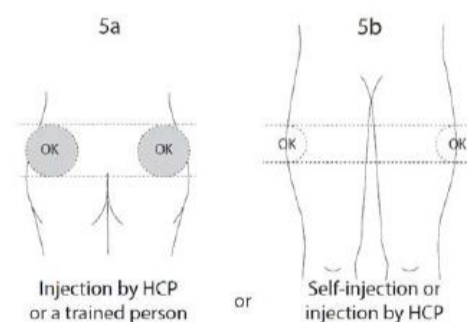
If any of the above apply, you should contact your doctor or pharmacist.

3. Wash hands with soap.
4. Tear-open the pouch along the dotted line and take out the pre-filled syringe. The content of the pre-filled syringe is a semi-solid phase having a gel-like appearance, with viscous characteristics and a colour varying from white to pale yellow. The supersaturated solution can also contain micro bubbles that can clear up during injection. These differences are normal and do not interfere with the quality of the product.



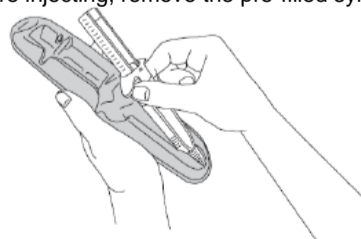
After opening the protective laminated pouch, the product should be administered immediately.

5. Select an injection site:
 - 5a. If a healthcare professional (HCP) or someone else like a trained family member or friend is doing the injection: use the superior external (upper, outer) quadrant of the buttock or the upper outer thigh for injection.
 - 5b. If you are injecting yourself: use the upper outer part of your thigh.

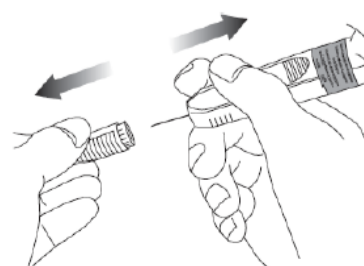


Alternate the injection site between the right and left side each time you receive an injection of Somatuline Autogel. Avoid areas with moles, scar tissue, reddened skin, or skin that feels bumpy.

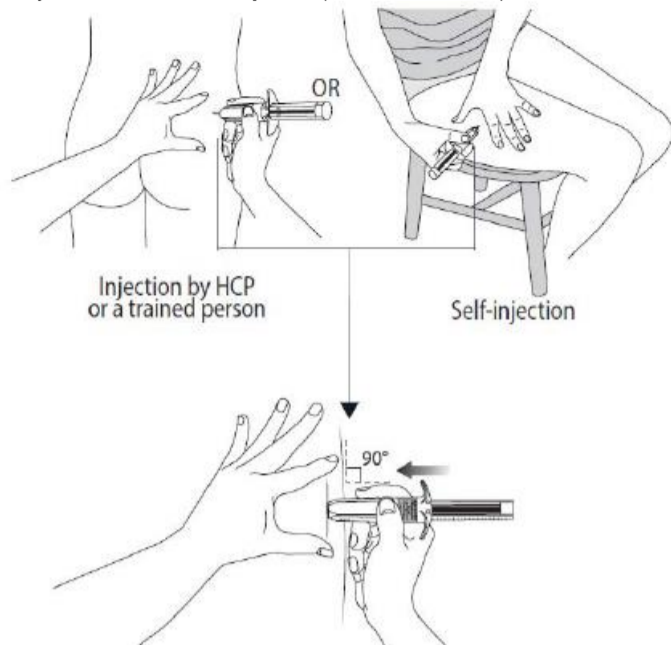
6. Clean the injection site.
7. Before injecting, remove the pre-filled syringe from its tray. Discard the tray



8. Remove the needle cap, by pulling off, and discard it.



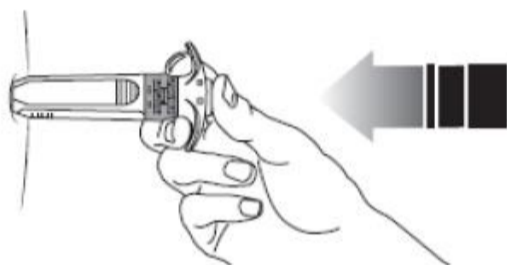
9. **Flatten** injection area using the thumb and index finger of the hand not holding the pre-filled syringe to stretch the skin. **Do not pinch** the skin. Use a strong, straight dart-like motion to **quickly insert** the needle **perpendicular** to the skin (90-degree angle), all the way into the skin. It is very important that you insert the needle **completely**. You should not see any needle once it is fully inserted. **Do not aspirate** (do not draw back).



10. Release injection site that has been flattened by your hand. Push plunger with **steady very firm pressure**. The medication is thicker and harder to push than you might expect. Typically 20 seconds are needed. Inject the **full dose and give a final push** to make sure you can not depress it any further.



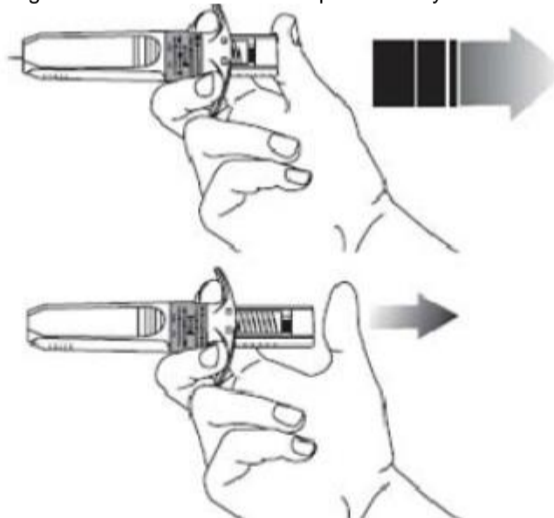
Note: maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.



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)
- Redness, pain, warmth and swelling at the injection site that may feel fluid-filled when pressed, fever – this may be a sign of abscess
- Sudden, severe pain in the upper right or centre abdomen that may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever – this may be a sign of inflammation of the gallbladder (cholecystitis)
- Pain in the upper right part of your belly (abdomen), fever, chills, yellowing of the skin and eyes (jaundice), nausea, vomiting, clay-coloured stools, dark urine, tiredness – these may be signs of inflammation of the bile duct (cholangitis)
- Decrease in pancreatic enzymes. As lanreotide may affect the release of pancreatic enzymes involved in food digestion, you may have symptoms such as fatty stools, loose stools, abdominal bloating or weight loss.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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 stated 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 in order to protect from light.

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

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 120 mg

The other ingredients are:

Water for injection

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).

Manufacturer

Ipsen Pharma Biotech, Parc d'activités du plateau de Signes, Chemin départemental N°402, 83870 Signes, France.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder.

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Parallel Product Authorisation number: PPA0465/478/001

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Is this leaflet hard to see or read? Phone +353 (0) 1 8356 700 and ask for help.

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