

SOMATULINE LP 120 mg prolonged-release solution for injection in pre-filled syringe

Lanreotide

Framed

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

- Keep this leaflet. You might need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed. Do not give this to anyone else. 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 also applies to any side effects that are not mentioned in this leaflet. See section 4.

What does this booklet contain ?

1. What is SOMATULINE LP 120 mg, prolonged-release solution for injection in a pre-filled syringe and in which cases is it used?
2. What should I know before using SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe?
3. How to use SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe?
4. What are the possible side effects?
5. How to store SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe?
6. Contents of the pack and other information.

1. WHAT SOMATULINE LP 120 mg, prolonged-release solution for injection in pre-filled syringe IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group - ATC code: H01C B03

What is SOMATULINE LP120 mg and what is it used for?

SOMATULIN LP 120 mg is a prolonged-release form of lanreotide. Lanreotide (the active substance) belongs to a family of medicines called 'growth hormone inhibitors'. It is similar to another substance (hormone) called 'somatostatin'.

Lanreotide lowers the levels of certain hormones in the body, such as growth hormone (GH) and IGF-1. It inhibits the release of certain hormones in the digestive tract as well as intestinal secretions. It also helps decrease or stop the growth of certain advanced tumors of the intestine and pancreas (called neuroendocrine tumors).

SOMATULINE LP120 mg , prolonged-release injectable solution in prefilled syringe is used:

- In the long term treatment of acromegaly (a disease in which the body produces too much growth hormone).
- In the treatment of symptoms associated with acromegaly, such as fatigue, headache, sweating, joint pain and numbness in hands and feet.
- In the treatment of symptoms such as hot flashes and diarrhea, which can occur in patients with certain tumors called carcinoid tumors.
- In the treatment and control of growth in some advanced tumors of the intestine and pancreas, called neuroendocrine tumors Gastroenteropancreatic pancreatic, when these tumors can not be removed by surgery.

2. WHAT YOU NEED TO KNOW BEFORE USING SOMATULINE LP 120 mg, prolonged-release solution for injection in pre-filled syringe?

Do not use SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe:

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

Warnings and Precautions

Talk to your doctor or pharmacist before using SOMATULINE LP 120 mg, prolonged-release solution for injection in a pre-filled syringe:

- **If you are diabetic** . Lanreotide can affect blood sugar levels. In this case, your doctor may find it necessary to check your blood sugar level and possibly change your anti-diabetic treatment while you are taking lanreotide.
- **If you have gallstones** . Lanreotide can promote the formation of gallstones in the gallbladder. Regular monitoring of the gallbladder may be necessary in this case. Your doctor may decide to stop treatment with lanreotide if complications from gallstones occur.
- **If you have thyroid problems** . Lanreotide may slightly decrease the functioning of your thyroid.
- **If you have heart problems** . Sinus bradycardia (slowing of the heart rate) may occur during treatment with lanreotide. If you have bradycardia, you should be especially careful when starting treatment with lanreotide.

If you are in any of the situations described above, tell your doctor or pharmacist before using SOMATULINE LP 120 mg.

Children

The use of SOMATULINE LP 120 mg is not recommended in children.

Other medicines and SOMATULINE LP 120 mg prolonged-release solution for injection in pre-filled syringe

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should be especially careful if you are taking at the same time:

- Within ciclosporin (a drug which reduces the immune response, used after organ transplantation or in the case of autoimmune disease);
- An antidiabetic treatment (insulin, glitazones, repaglinide or sulphonylurea);
- A drug which slows the rhythm of the heart (such as beta-blockers).

In this case, your doctor may decide to change the dose of the associated medicines.

SOMATULINE LP 120 mg prolonged-release solution for injection in pre-filled syringe with food and drink

Not applicable.

Pregnancy and breast feeding

Pregnancy

You should not take SOMATULINE LP 120 mg during your pregnancy unless clearly necessary.

Feeding with milk

In the absence of data on the excretion of SOMATULINE LP 120 mg in human milk, SOMATULINE LP 120 mg should not be used during breast-feeding.

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

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.

Driving and using machines

Your ability to drive or use machines is unlikely to be affected by your treatment. However, side effects such as dizziness may occur with SOMATULIN LP. If you experience such effects, caution should be exercised while driving or using machines.

SOMATULINE LP 120 mg prolonged-release solution for injection in pre-filled syringe contains

Not applicable.

3. HOW TO USE SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe?

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if in doubt.

The solution for injection in the pre-filled syringe is a ready-to-use supersaturated solution of lanreotide forming an autogel with a whitish and translucent appearance.

Dosage

• Treatment of acromegaly and symptoms associated with acromegaly

The recommended dose is one injection every 28 days.

Your doctor may adjust the dose given by choosing one of the 3 available strengths of SOMATULINE LP (60 mg, 90 mg or 120 mg).

If you are well controlled with your treatment, your doctor may change the frequency of injections to 1 injection of SOMATULINE LP 120 mg every 42 or 56 days.

Your doctor will decide how long you need to take this treatment.

•Treatment of symptoms (such as hot flashes and diarrhea) associated with carcinoid tumors

The recommended dose is one injection every 28 days.

Your doctor may adjust the dose given by choosing one of the 3 available strengths of SOMATULINE LP (60 mg, 90 mg or 120 mg).

Your doctor will decide how long you need to take this treatment.

•Treatment of digestive neuroendocrine tumors advanced bowel and pancreas, where they can not be removed by surgery

The recommended dose is one injection of 120 mg every 28 days.

Your doctor will decide how long you need to be given SOMATULINE LP for tumor control.

Administration mode

SOMATULINE LP should be injected under the skin (deep subcutaneous route).

The injection should be given by a healthcare professional or by someone close to you (family member or friend) or by yourself, after having received appropriate training from a healthcare professional.

The decision for administration by yourself or by another trained person will be made by your doctor. If you are in doubt about how to give this injection, please contact your doctor or healthcare professional for further advice or training.

If the injection is performed by a healthcare professional or by a trained person close to you, it should be performed in the upper outer quadrant of the buttock or in the upper outer side of the thigh (see figures 5a and 5b below).

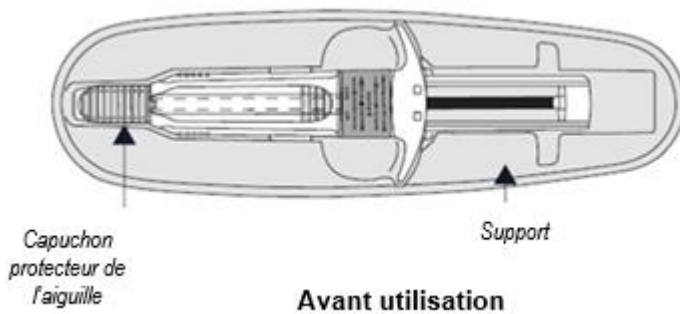
If you are giving the injection yourself (self-injection), it should be done on the upper outer side of the thigh (see figure 5b below).

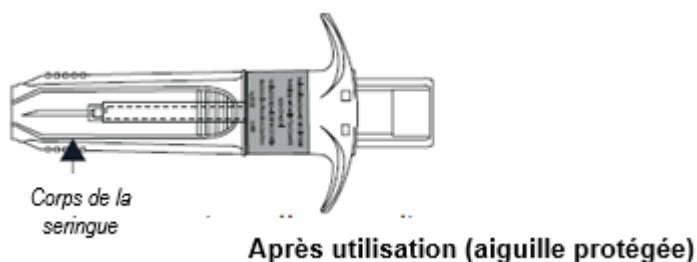
Instructions for the administration of the product:

Warning: read the following instructions carefully before injecting. This is a deep subcutaneous injection which requires a specific technique, different from the normal subcutaneous injection.

The following instructions explain how to inject SOMATULINE LP

SOMATULINE LP comes in the form of a single-use, ready-to-use, pre-filled syringe fitted with an automatic safety system. The needle retracts automatically after complete administration of the product to avoid accidental needle stick injuries.





1. **Take SOMATULINE LP out of the refrigerator 30 minutes before administration** . The injection may be painful if the medicine is cold. Keep the plastic protective case **sealed** until you are **ready** to inject.



2. **Warning** : Before opening, check that the protective case is intact and that the expiration date has not passed.

Do not use the pre-filled syringe:

- If you drop or damage the pre-filled syringe, or if the pre-filled syringe or the packaging seem damaged to you;
- If the expiry date has passed; it appears on the outer box and on the protective case.

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

3. Wash your hands with soap.

4. Open the protective case along the dotted line and take out the pre-filled syringe. The contents of the pre-filled syringe appear as a viscous semi-solid gel-like phase, white to pale yellow in color. The supersaturated solution may also contain microbubbles which may disappear during the injection. These differences are normal and do not affect the quality of the product.

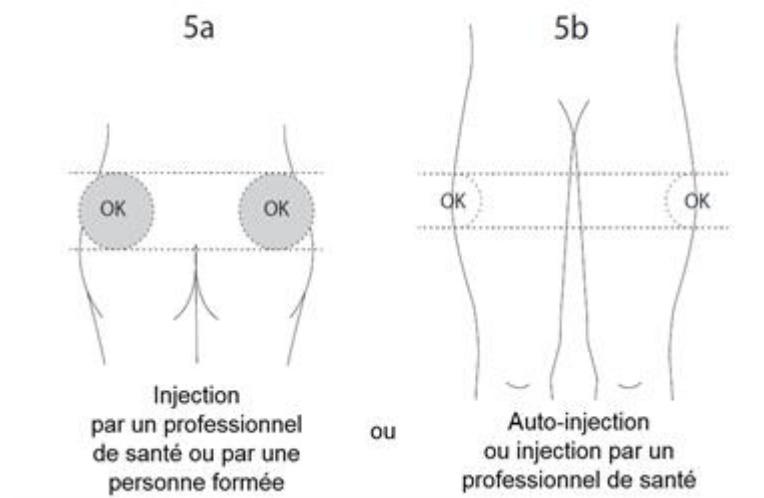


After opening the protective plastic case, the product should be administered immediately.

5. Determine the injection site:

5a or 5b. If the injection is performed by a healthcare professional or by a person close to you who has received appropriate training: injection in the upper outer quadrant of the buttock or in the upper outer surface of the thigh,

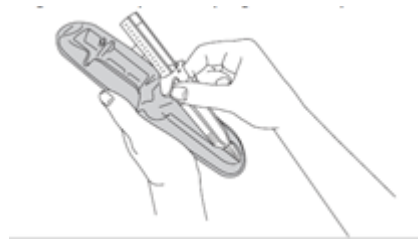
5b. If you are injecting yourself (self-injection): injection into the top of the outer thigh.



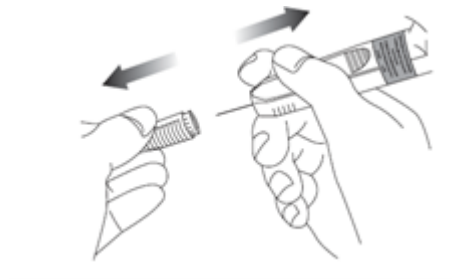
Alternate the injection site between the right side and the left side with each injection of SOMATULINE LP. Avoid areas with moles, scars, reddened or bumpy skin .

6. Disinfect the injection site.

7. Before injecting, remove the pre-filled syringe from its holder. Discard the media.



8. Pull the protective needle cap off the needle and discard it.



9. **Stretch** the skin around the injection area between the thumb and forefinger of the hand that is not holding the syringe to flatten this area. **Do not pinch the skin** . Use a firm motion, such as with a dart, to **quickly insert** the needle **perpendicular** to the skin (90 degree angle), along its entire length.

It is very important to insert the needle **all the way** . No part of the needle should be visible when it is fully inserted.

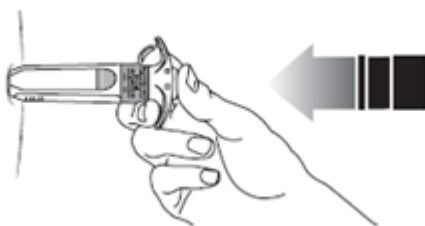
Do not aspirate (do not pull the plunger).



10. Release the injection site that was flattened with your hand. Push the plunger with **very firm and constant pressure**. The medicine is thicker and harder to push than expected. Typically 20 seconds are required. Inject **the full dose** and give a **final squeeze** to make sure you cannot push any further



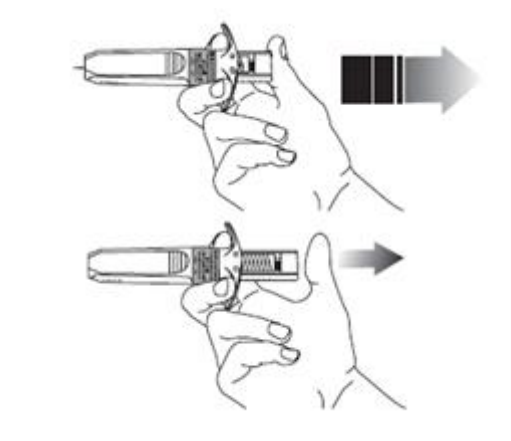
Note: Keep pressure on the plunger with your thumb to avoid triggering the automatic safety system.



11. Withdraw the needle from the skin without releasing pressure on the plunger.



12. Release the pressure on the plunger. The needle will automatically retract into a protective case where it will be locked permanently.



13. Lightly press the injection site with a dry cotton or sterile gauze to prevent bleeding. **Do not rub or massage** the injection site after administration.

14. Dispose of the used syringe properly. Your doctor or nurse will explain the special precautions for disposing of used injection equipment. **Do not throw** the used syringe in your household trash. **If you use more SOMATULINE LP 120 mg, prolonged-release solution for injection in a pre-filled syringe than you should**

Consult your doctor.

If you have received too much SOMATULINE LP, you may experience more side effects or more severe side effects (see section 4 Possible side effects).

If you forget to use SOMATULINE LP 120 mg, prolonged-release solution for injection in pre-filled syringe

As soon as you notice that you have missed an injection, tell your doctor who will advise you on the best time to give your next injection.

Do not give yourself an extra injection to make up for a forgotten injection without discussing it with your doctor first.

If you stop using SOMATULINE LP 120 mg, prolonged-release solution for injection in a pre-filled syringe

Interrupting more than one injection or stopping your treatment with SOMATULINE LP prematurely may affect the success of your treatment. Ask your doctor for advice before stopping your treatment.

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

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

Tell your doctor straight away if you notice any of the following side effects:

- If you are thirsty or if you feel more tired than usual and if you have dry mouth. These signs may indicate that you have high blood sugar or that you are developing diabetes.
- if you feel hungry, shaking, sweating more than usual, or if you feel confused. These signs may indicate that you have low blood sugar.

These side effects are common; they can affect up to 1 in 10 people.

Tell your doctor immediately if you notice that:

- Your face becomes red or swollen, or if you have pimples or a rash.
- You feel your chest tighten, you are embarrassed breathing or wheeze.
- You feel low, maybe in connection with a drop in blood pressure.

These signs can be the result of an allergic reaction. The frequency of this undesirable effect is not known because the available data do not allow an estimate.

Other side effects:

If you notice any of the side effects listed below, please tell your doctor or pharmacist.

The most common side effects are gastrointestinal disturbances, gallbladder problems and injection site reactions.

The side effects that may occur with SOMATULINE LP are listed below in order of frequency.

Very common (may affect more than 1 in 10 people)

- Diarrhea, loose stools, abdominal pain
- Gallstones and other gallbladder problems. You may have symptoms such as sudden severe abdominal pain, high fever, jaundice (skin and whites of the eyes turning yellow), chills, loss of appetite, itching.

Common (may affect up to 1 in 10 people)

- Weight loss
- Lack of energy
- Slow heartbeat
- Very important Feeling tired
- Decreased appetite
- Feeling of weakness
- Excess fat in the stool
- Sensation of dizziness, headaches
- Hair loss or decreased hair development
- Pain in ligaments, muscles, tendons and bones

- Reactions at the injection level such as pain, itching or induration
- Abnormal liver tests and pancreatic; changes in blood sugar levels
- Nausea, vomiting, constipation, flatulence, bloating or stomach discomfort, indigestion
- Biliary dilation (enlargement of the bile ducts between the liver and the gallbladder and the intestine). You may experience symptoms such as stomach pain, nausea, jaundice, and fever.

Uncommon (may affect up to 1 in 100 people)

- Hot Flashes
- Difficulty falling asleep
- Color change stool
- Changes in blood alkaline phosphatase and sodium levels.

Unknown frequency (frequency cannot be estimated from the available data)

- Sudden and intense pain in the lower part of the stomach. This can be a sign of inflammation of the pancreas (pancreatitis).
- Redness, pain, heat and swelling at the injection site that can seem filled liquid when pressed, and fever. This can be a sign of an abscess.
- Severe pain and sudden upper right abdomen or in the center, which can radiate to the shoulder or back, tenderness of the abdomen, nausea, vomiting and high fever. This could be a sign of gallstones (cholecystitis).
- Pain in the upper right of your belly (abdomen), fever, chills, yellowing of the skin and eyes (jaundice), nausea, vomiting, clay-colored stools, dark urine, and tiredness. These may be signs of inflammation of the bile duct (cholangitis).

As lanreotide can affect blood sugar levels, your doctor may find it necessary to check your blood sugar level, especially at the start of treatment.

Likewise, since this type of medicine can cause gallbladder problems, your doctor may find it necessary to monitor your gallbladder when starting treatment with SOMATULINE LP and then periodically while treatment continues.

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOMATULINE LP 120 mg prolonged-release solution for injection in a pre-filled syringe?

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

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiration date refers to the last day of that month.

Store SOMATULINE LP 120 mg at a temperature between + 2 ° C and + 8 ° C (in the refrigerator), in its original packaging to protect it from light.

After removal from the refrigerator, the product that has remained in its sealed protective case may be returned to the refrigerator for storage for later use, provided it has not undergone more than three temperature excursions and has been stored for less than 24 hours in total at a temperature below 40 ° C .

Each syringe is individually packaged.

Do not throw away any medicine 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 PACKAGE AND OTHER INFORMATION

What SOMATULINE LP 120 mg contains, prolonged-release solution for injection in a pre-filled syringe

- The active substance is:

Lanreotide 120 mg
(as lanreotide acetate)

For a pre-filled syringe.

- The other ingredients are: Water for injections, acetic acid (for pH adjustment).

What SOMATULINE LP 120 mg, prolonged-release solution for injection in pre-filled syringe looks like and contents of the pack

SOMATULINE LP 120 mg is a viscous, prolonged-release solution for injection in a ready-to-use pre-filled syringe, with an automatic safety system.

Each pre-filled syringe is packaged in a protective plastic case and in a cardboard box

The product is a semi-solid preparation, white to pale yellow.

Box containing 1 syringe of 0.5 ml with safety system and 1 needle (1.2 mm x 20 mm).

Marketing authorization holder

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