SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg,

prolonged-release solution for injection in a pre-filled syringe.

Please read carefully the whole of this leaflet carefully before using this medication.
Keep this leaflet, you may need to read it again.
If you have questions, or in any doubt, please ask your doctor or your pharmacist for more information.
This medication has been prescribed for you personally. Do not give it to anyone else, even if the symptoms are identical, as this could be dangerous.

In this leaflet:

1. WHAT IS SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe AND WHEN SHOULD IT BE USED?

SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe is a solution for injection containing 60 mg, 90 mg or 120 mg of lanreotide.
Somatuline Autogel is supplied in a pre-filled syringe (clear polypropylene) fitted with an automatic safety system, a needle (stainless steel), a plastic needle sheath (LDPE) and a plunger stopper (bromobutyl rubber).
Each pre-filled syringe is packed in a laminated pouch (polyethylene teraphtalate/aluminium/polyethylene laminate) and a cardboard box.
Box of one 0.5 ml pre-filled syringe with an automatic safety system and one needle (1.2 mm x 20 mm).
This medication contains lanreotide (active substance), water for injections (excipient) and glacial acetic acid (for pH adjustment) (excipient).

Deep sub-cutaneous route.
ANTIGROWTH HORMONE.

This medication is used to treat acromegaly when secretions of Growth Hormone (GH) and IGF-1 remain abnormal after surgery and/or radiation therapy and used in the treatment of the clinical symptoms associated with acromegaly.
It is also used in the treatment of the clinical symptoms of certain endocrine digestive diseases.

2. INFORMATION REQUIRED BEFORE USING SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe:

Do not use SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe in the following cases:
- complicated, untreated lithiasis of the bile ducts,
- pregnancy and lactation,
- allergy to lanreotide or related medications.

Precautions for use:
- In diabetics, blood glucose levels should be monitored more frequently and the dose of the anti-diabetic treatment may need to be adjusted.
- An ultrasound scan of the gall bladder should be conducted systematically both at the start and in the course of the treatment with SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe. Gallstones occurring during treatment are usually asymptomatic.
- The dose may need to be adjusted in subjects with renal and hepatic impairment.
- No dosage adjustment is necessary in elderly patients with normal renal and hepatic function.

Pregnancy - Breast-feeding
This medication is contraindicated in pregnant and breast feeding women.
If you discover you are pregnant in the course of the treatment, please consult your doctor.

Driving and using machines
Not applicable

List of those excipients with well known effects:
Not applicable.

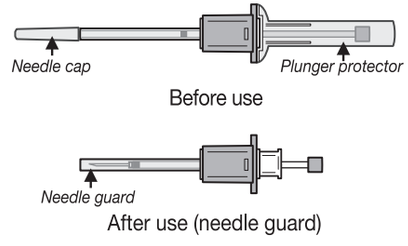
Use of other medications:
Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medication, even if this is non-prescription medication.

3. INSTRUCTIONS FOR THE USE OF SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe

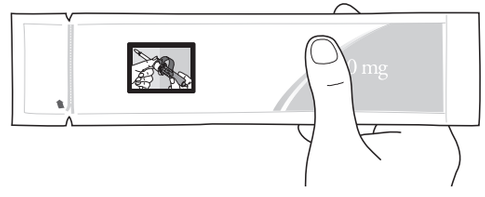
The solution for injection contained in the pre-filled syringe corresponds to a ready-for-use, supersaturated solution of lanreotide that forms a whitish and translucent autogel.

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.

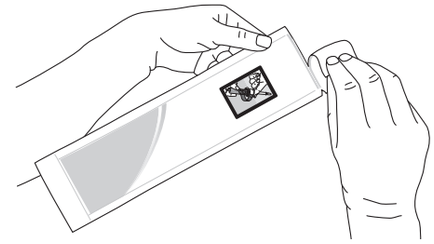


1. Remove Somatuline Autogel from the refrigerator 30 minutes prior to administration. Keep pouch sealed until just prior to injection.
2. Before opening the pouch, check that it is intact and that the medication has not expired. The expiration date is printed on the outer carton and the pouch. DO NOT USE IF THE MEDICATION HAS EXPIRED OR IF THE LAMINATED POUCH IS DAMAGED IN ANY WAY.

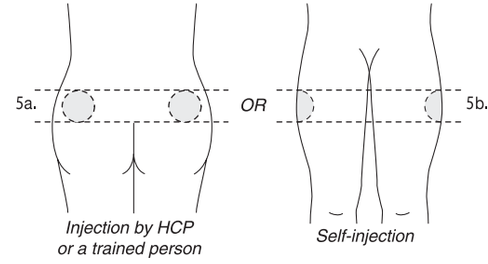


3. Wash hands with soap and ensure there is a clean area for preparation.

4. Tear-open the pouch and take out the pre-filled syringe.

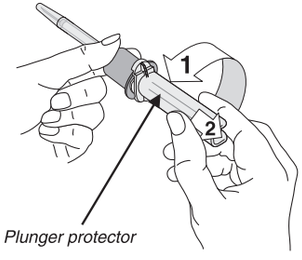


5. Select an injection site:
5a. for injection by healthcare professional (HCP) or someone else like a trained family member or friend: the superior external quadrant of the buttock, or
5b. if you will be injecting yourself: the upper outer part of your thigh.

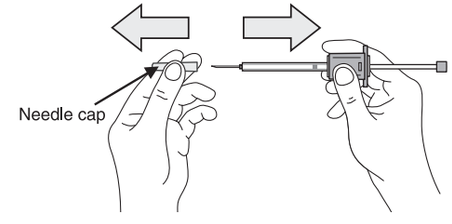


- **Alternate the injection site** between the right and left side each time you receive an injection of Somatuline Autogel.

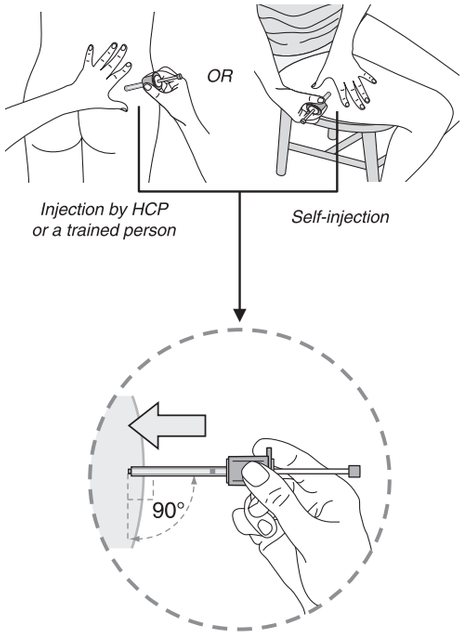
6. Clean the injection site without rubbing the skin.
7. Twist and pull off the plunger protector and discard it.



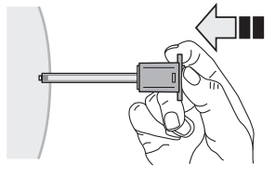
8. Remove the needle cap and discard it.



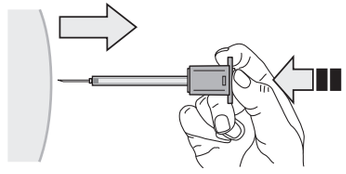
9. Hold the skin around the injection site flat using your thumb and index finger. Without folding or pressing on the skin at the injection site, rapidly insert the needle to its full length (deep subcutaneous injection), perpendicular (90°) to the skin.



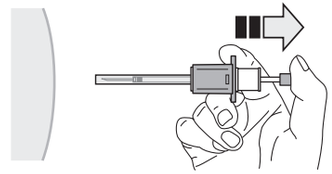
10. Inject the drug **slowly. Typically 20 seconds are needed**. Inject the full dose until the plunger cannot be depressed any further. At this point, you will hear a "click".
Note: maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.



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



12. Then release 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 appropriately. Your doctor or nurse will explain how to discard the used material for injection. DO NOT dispose of the device in your general household rubbish.

Dosage:
One injection every 28 days.
Your doctor may adjust the dose or the injection frequency depending on the results of your physical examination (clinical symptoms) and/or blood tests (hormone levels).
If you feel the effect of SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe is either too strong or too weak, please consult your doctor or pharmacist.

Method and/or route or administration:
Deep sub-cutaneous route into outer, upper quadrant of the buttock.
Injection can be made either by the patient himself (self-injection) or by a person around him, according to the instructions for use above, after appropriate training by a health care professional.
If injection is made by the patient himself (self-injection), injection should be performed in the upper outer thigh.
The needle should be inserted to its full length, perpendicularly to the skin, without pinching.

Treatment duration:
Please follow your prescription.

If you have been administered more SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe than you should have:
Consult your doctor or pharmacist immediately.

If you forget to administer the SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe :
Please consult your doctor.
Do not take a double dose to compensate for the dose you forgot.

4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS OF SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe?

Like all medicines, SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe can have side effects.
The most commonly reported undesirable effects are gastro-intestinal:
- very common and common: diarrhoea or soft stool, abdominal pain, nausea, flatulence, constipation, gallstones;
- more rarely: increased bilirubin.

The following undesirable effects have also been reported:
- moderate and transient pain at the injection point, sometimes associated with local redness, induration or itching. These reactions are reversible;
- more rarely, loss of energy, fatigue, dizziness, hot flushes, heavy legs, malaise, headache, vomiting, decreased libido, itching and increased sweating;
- a few rare cases of disturbances in blood glucose levels (glycaemia) have been reported.

If you are diabetic, your doctor should check your blood glucose levels and possibly suspend anti-diabetic treatment during the use of SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg.

5. HOW SHOULD SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, prolonged-release solution for injection in a pre-filled syringe BE STORED?

Keep out of the reach and sight of children.
Store at 2°C – 8°C (refrigerator) in the original packaging.

Do not use after the expiration date marked on the packaging and label.

6. FURTHER INFORMATION

The active substance is :

SOMATULINE AUTOGEL 60 mg :
Lanreotide 60 mg
(presented as lanreotide acetate)
For one pre-filled syringe

SOMATULINE AUTOGEL 90 mg :

Lanreotide 90 mg
(presented as lanreotide acetate)
For one pre-filled syringe

SOMATULINE AUTOGEL 120 mg :

Lanreotide 120 mg
(presented as lanreotide acetate)
For one pre-filled syringe

The others ingredients correspond to :
Water for injections, glacial acetic acid (for pH adjustment).

What Somatuline Autogel looks like and contents of the pack
SOMATULINE AUTOGEL 60 mg, 90 mg, 120 mg, is a prolonged-release 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.

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

Name and address of marketing authorisation holder/ Exploitant

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FRANCE

Manufacturer:
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Parc d'Activités du Plateau de Signes
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FRANCE

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