PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SOMATULINE® AUTOGEL® 60, solution for injection

SOMATULINE® AUTOGEL® 90, solution for injection

SOMATULINE® AUTOGEL® 120, solution for injection

Lanreotide

Sugar free.

Read all of this leaflet carefully before you start receiving SOMATULINE AUTOGEL.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- SOMATULINE AUTOGEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SOMATULINE AUTOGEL is and what it is used for.
2. What you need to know before you receive SOMATULINE AUTOGEL.
3. How SOMATULINE AUTOGEL is used.
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

SOMATULINE AUTOGEL is an injectable medicine used for:

- The treatment of acromegaly (a condition where your body produces too much growth hormone), when surgery or radiotherapy has failed.

- The treatment of symptoms associated with carcinoid tumours, such as flushing and soft stools.
- 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 receive SOMATULINE AUTOGEL

You should not be administered SOMATULINE AUTOGEL:

- If you are allergic (hypersensitive) to lanreotide, somatostatin or medicines from the same family (analogues of somatostatin), or any other ingredient of SOMATULINE AUTOGEL (see section 6).
- If you have gallbladder problems.
- If you are pregnant or breastfeeding.

Warnings and precautions:

Tell your doctor or healthcare professional before being given the injection if:

- You have liver or kidney problems.
- You are diabetic. SOMATULINE AUTOGEL may affect your blood sugar levels. If you have diabetes, carefully follow your doctor's instructions for monitoring your blood sugar levels. Your antidiabetic medicines may need to be adjusted.
- Your gallbladder has not been removed. SOMATULINE AUTOGEL may lead to gallstone formation. Your doctor may check your gallbladder before starting and during treatment with SOMATULINE AUTOGEL. Your doctor may decide to stop treatment with SOMATULINE AUTOGEL if complications arising from gallstones occur.
- You have thyroid problems. SOMATULINE AUTOGEL may slightly decrease thyroid function.
- You have cardiac disorders. Sinus bradycardia (slower heartbeat) may occur under treatment with SOMATULINE AUTOGEL. If you suffer from bradycardia, you should be especially careful when starting treatment with SOMATULINE AUTOGEL.

If any of the above applies to you, consult your doctor or pharmacist before using SOMATULINE AUTOGEL.

SOMATULINE AUTOGEL is not recommended for use in children and adolescents.

Other medicines and SOMATULINE AUTOGEL:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor about all the medicines you are taking, have recently taken or might take, especially:

- Insulin or other diabetes medicines (including repaglinide or medicines called glitazones or sulphonylureas).
- Ciclosporin (a medicine that decreases the immune reaction, taken after organ transplant or for an autoimmune disease).
- Medicines that slow your heartbeat (bradycardia-inducing medicines, such as beta blockers).
- Bromocriptine (a medicine used in the treatment of certain types of tumours of the pituitary gland, Parkinson's disease, hyperprolactinaemia [high levels of a substance in the body called prolactin] or to prevent lactation following childbirth).
- Quinidine (medicine used to treat an irregular heartbeat).

SOMATULINE AUTOGEL may interfere with the breakdown of some medicines by the liver enzymes. Tell your doctor or pharmacist about all the medicines you are taking.

Pregnancy, breastfeeding and fertility

You should not receive SOMATULINE AUTOGEL if you are pregnant.

If you are being treated with SOMATULINE AUTOGEL, you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving SOMATULINE AUTOGEL.

Driving and using machines

SOMATULINE AUTOGEL can make you feel dizzy, tired or slowed down. You should not drive or

operate machinery if you feel like that.

3. How SOMATULINE AUTOGEL is used

Do not share medicines prescribed for you with any other person.

Always use SOMATULINE AUTOGEL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- You will receive a SOMATULINE AUTOGEL injection every 4 weeks as directed by your doctor.
- Your doctor will tell you how much SOMATULINE AUTOGEL you need and for how long you need to receive it.
- Remove SOMATULINE AUTOGEL from the refrigerator 30 minutes prior to administration, but keep the pouch sealed during this time. Refer to section 5 for more information.
- SOMATULINE AUTOGEL is injected deep under the skin of the upper outer area of your buttock or the upper outer thigh by a healthcare professional. The injection site should be changed (alternated) between your right and left side each time you receive an injection of SOMATULINE AUTOGEL. See **INSTRUCTIONS FOR USE** at the end of this leaflet.
- If the dose of SOMATULINE AUTOGEL you receive stays stable (the same), and after you have had appropriate training by a healthcare professional, SOMATULINE AUTOGEL may be administered either deep under the skin of the upper outer thigh by yourself or deep under the skin of the upper outer area of your buttock or the upper outer thigh by a trained person. See **INSTRUCTIONS FOR USE** at the end of this leaflet.
- The decision of self-administration or administration by another trained person should be taken by your doctor.
- Each syringe is intended for single use only.

If you have the impression that the effect of SOMATULINE AUTOGEL is too strong or too weak for you, tell your doctor.

If you receive more SOMATULINE AUTOGEL than you should

If you have received or accidentally injected too much SOMATULINE AUTOGEL, contact your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of SOMATULINE AUTOGEL

As soon as you realise that you have missed an injection, contact your doctor, who will give you advice about the timing of your next injection.

Effects when treatment with SOMATULINE AUTOGEL is stopped

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 SOMATULINE AUTOGEL, ask your doctor or pharmacist.

4. Possible side effects

SOMATULINE AUTOGEL can have side effects.

Not all side effects reported for SOMATULINE AUTOGEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SOMATULINE AUTOGEL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop using SOMATULINE AUTOGEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SOMATULINE AUTOGEL. You may need urgent medical attention or hospitalisation.

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

- feeling hungry, shaky, sweating more than usual or feeling confused – these may be signs of low blood sugar levels
- 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
- severe and sudden abdominal (stomach) pain, the pain may spread to the shoulder or back, tenderness of the abdomen, nausea, vomiting, high fever, jaundice (yellowing of the skin and whites of the eyes), chills, loss of appetite, itchy skin – these may be signs of gallbladder problems.

These are all serious side effects. You may need urgent medical attention.

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

The most commonly expected side effects are gastrointestinal (stomach) disorders, gallbladder problems and injection site reactions. The side effects below are listed according to their frequencies.

Frequent:

- diarrhoea, loose stools, stomach 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
- slower heartbeat
- weight loss
- feeling very tired, lack of energy
- feeling generally weak
- pain that affects muscles, ligaments, tendons and bones
- feeling dizzy, having a headache
- loss of hair or less hair growth

- reactions where the injection is given such as pain, itching, swelling or hard skin
- nausea, vomiting, constipation, passing wind, stomach bloating or discomfort, indigestion
- abnormal liver and pancreas test results
- changes in blood sugar levels, diabetes mellitus
- 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
- decreased appetite
- excess fat in the stools.

Less frequent:

- hot flushes
- difficulty sleeping (insomnia)
- a change in the colour of the stools, a feeling that you need bowel movements (rectal pain)
- leg pain
- changes to sodium and alkaline phosphatase levels, shown in blood tests
- skin nodules
- drowsiness
- decreased libido
- increased sweating
- tiredness.

Unknown:

- 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 ducts (cholangitis).

Tell your doctor if you have any side effect that bothers you or that does not go away.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- Acino Pharma (Pty) Ltd: E-mail: drugsafety_ZA@acino.swiss or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SOMATULINE AUTOGEL.

5. How to store SOMATULINE AUTOGEL

Store all medicines out of the reach of children.

Store at 2 °C – 8 °C (in a refrigerator) in its original package in order to protect from light.

Do not freeze. Do not remove from the carton until required for use.

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 72 hours at below 40 °C.

After opening the protective laminated bag, SOMATULINE AUTOGEL should be administered immediately.

Do not use after the expiry date stated on the pack.

Do not dispose of unused medicine or waste material in drains or sewerage systems.

Return all unused medicine to your pharmacist and dispose of waste material in accordance with local requirements.

6. Contents of the pack and other information

What SOMATULINE AUTOGEL contains

Each pre-filled syringe contains the active substance lanreotide acetate, equivalent to 60 mg, 90 mg and 120 mg lanreotide, respectively.

The other ingredients are glacial acetic acid (for pH adjustment) and water for injection.

What SOMATULINE AUTOGEL looks like and contents of the pack:

White to pale yellow semi-solid phase in a pre-filled syringe.

A carton containing one 0,5 mL polypropylene pre-filled syringe fitted with an automatic safety system with a plunger stopper made from grey bromobutyl rubber, coated with silicone, and a stainless steel needle covered by a plastic cap.

Each ready to use pre-filled syringe is placed into a plastic tray and packed in a laminated pouch and a cardboard box.

A box of one 0,5 mL pre-filled syringe with an attached needle (1,2 mm x 20 mm).

Holder of certificate of registration:

Acino Pharma (Pty) Ltd

106, 16th Road

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1686

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SOMATULINE AUTOGEL 60: 45/21.12/1022

SOMATULINE AUTOGEL 90: 45/21.12/1023

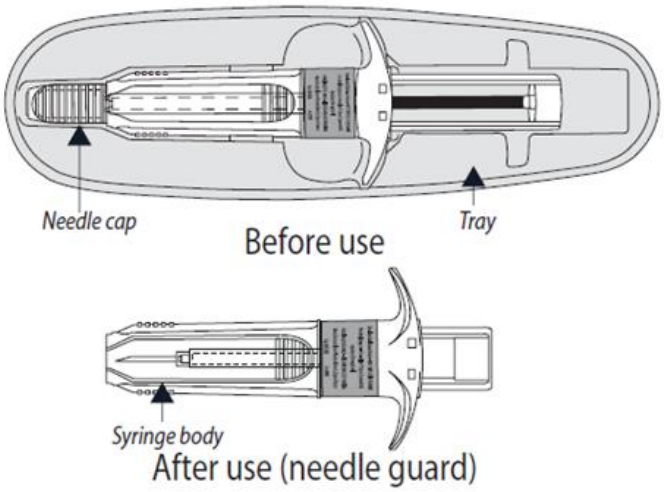
SOMATULINE AUTOGEL 120: 45/21.12/1024

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 prevent needle stick injury.



1. **Remove** SOMATULINE AUTOGEL from **the refrigerator 30 minutes prior to administration**. Injection of cold medicine may be painful. Keep laminated pouch sealed until just prior to injection. Refer to section 5 of the Patient Information Leaflet for more information.



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

72 hours at below 40 °C.

2. **Attention:** Before opening the pouch, check that it is intact and that the medicine 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.



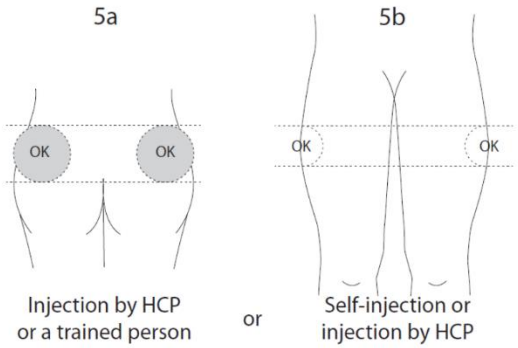
   After opening the protective laminated pouch, the product should be administered immediately.

5. Select an injection site:

   5a or 5b. 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.

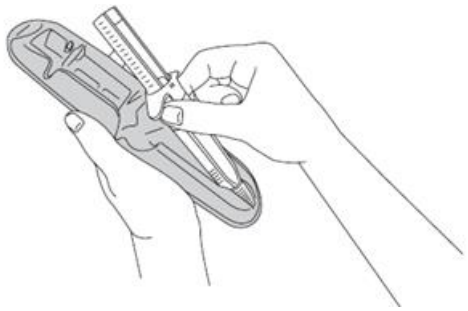
5b. If you are injecting yourself: use the upper outer part of your thigh.



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.

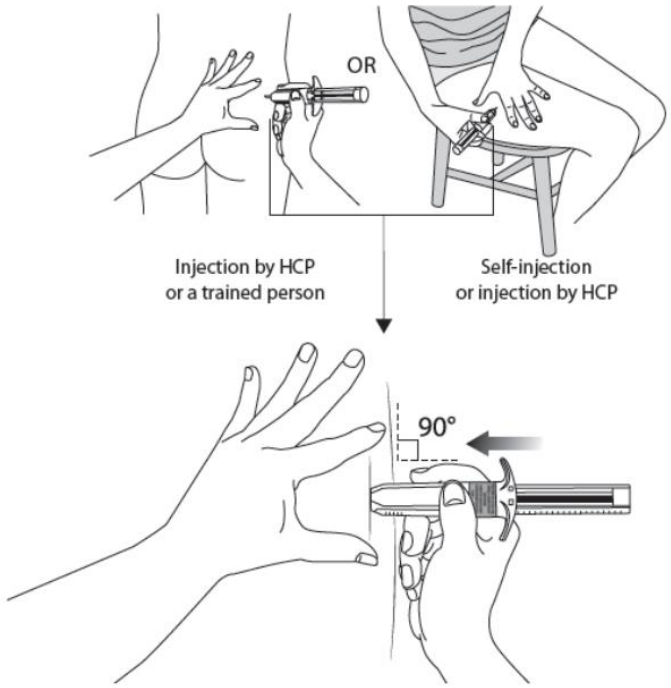
7. Before injecting, remove the pre-filled syringe from its tray. Discard the tray.



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

9. **Flatten** the 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.

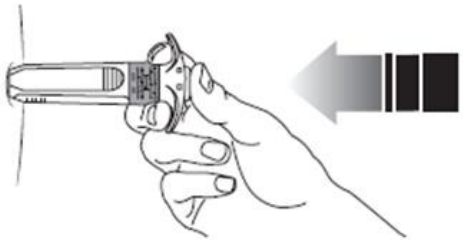
Do not aspirate (do not draw back).



10. Release injection site that has been flattened by your hand. Push plunger with **steady very firm pressure**. The medicine 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 cannot depress it any further.



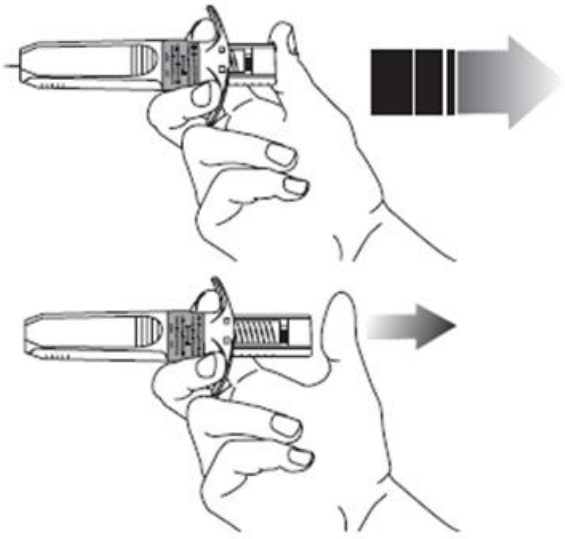
Note: Maintain pressure on the plunger with your thumb to avoid activation of the automatic safety system.



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



12. Then release 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 professional. **Do not dispose** of the device in your general household waste.