NOVARTIS

SANDOSTATIN® LAR® (octreotide acetate)

10 mg, 20 mg, 30 mg powder and solvent for suspension for injection

Patient Information Leaflet

Document status: Final

Approval date: 05 September 2021

SCHEDULING STATUS:

S4

SANDOSTATIN® LAR® 10 mg

(Dry vial - microspheres for injection)

SANDOSTATIN® LAR® 20 mg

(Dry vial - microspheres for injection)

SANDOSTATIN® LAR® 30 mg

(Dry vial - microspheres for injection)

SANDOSTATIN® LAR® SUSPENSION VEHICLE

Octreotide, 10 mg, 20 mg, 30 mg

Read all of this leaflet carefully before you are given SANDOSTATIN LAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

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

1. What SANDOSTATIN LAR is and what it is used for

SANDOSTATIN LAR is a slow release formulation of a synthetic compound derived from somatostatin. Somatostatin is normally found in the human body, where it inhibits the release of certain hormones such as growth hormone.

To treat acromegaly:

SANDOSTATIN LAR is used to treat people with acromegaly

• when treatment with another form of a somatostatin that is given every day by means of an injection under the skin (subcutaneously) has proved to be satisfactory;

• when other types of treatment for acromegaly (surgery or radiotherapy) are not suitable or haven't worked;

• after radiotherapy, to cover the interim period until the radiotherapy becomes fully effective.

To treat patients with carcinoid tumours:

SANDOSTATIN LAR is used to treat people with carcinoid tumours:

• when the symptoms of the carcinoid tumours are adequately controlled with another form of a somatostatin analogue that is given every day by means of an injection under the skin (subcutaneously)

• with VIPomas

2. What you need to know before you use SANDOSTATIN LAR

SANDOSTATIN LAR should not be administered to you :

• if you are allergic (hypersensitive) to octreotide or any of the other ingredients of SANDOSTATIN LAR listed in section 6 of this leaflet.

• if you are pregnant or breastfeeding your baby.

If any of these apply to you, tell your doctor before using SANDOSTATIN LAR.

Warnings and precautions

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

• you are taking other medicines to control blood pressure (beta-blockers or calcium channel blockers) or agents to control fluid and electrolyte balance. Dose adjustments may be necessary;

• you know that you have gallstones now, or have had them in the past or experience any complications like fever, chills, abdominal pain, or yellowing of your skin or eyes, tell your doctor, as prolonged use of SANDOSTATIN LAR may result in gallstone formation. Your doctor may wish to check your gallbladder periodically;

• you know that you have diabetes, as SANDOSTATIN LAR can affect blood sugar levels. If you are diabetic, your sugar levels should be checked regularly;

• you have a history of vitamin B_{12} deficiency; your doctor may wish to check your B_{12} level periodically;

• you receive long treatment with SANDOSTATIN LAR; your doctor may wish to check your thyroid function periodically.

Children and adolescents

There is little experience with the use of SANDOSTATIN LAR in children.

Elderly patients

There is little experience with the use of SANDOSTATIN LAR in elderly persons.

Other medicines and SANDOSTATIN LAR:

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Sandostatin LAR may interfere with some other medicines.

Tell your doctor if you are taking any of the following medicines:

• Cimetidine (medicine for heartburn or stomach ulcer)

• Ciclosporin (medicine taken after organ transplant or for some auto immune diseases)

• Bromocriptine (used to treat Parkinson's disease or pituitary tumours)

If you are taking a medicine to control your blood pressure (e.g. a beta blocker or a calcium channel blocker) or an agent to control fluid and electrolyte balance, your doctor may need to adjust the dosage.

If you are diabetic, your doctor may need to adjust your antidiabetic treatment.

If you are going to receive lutetium oxodotreotide treatment (a cancer medicine for treating tumours in the gut. This medicine is a radiopharmaceutical, which is a medicine that emits a small amount of radioactivity), your doctor may stop and/or adapt SANDOSTATIN LAR treatment.

Pregnancy and breastfeeding and fertility:

Pregnant women

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking SANDOSTATIN LAR.

Your doctor will discuss with you the potential risks of taking SANDOSTATIN LAR during pregnancy.

Women of child-bearing potential should use an effective contraceptive method during treatment.

Breastfeeding mothers

Mothers treated with SANDOSTATIN LAR should not breastfeed their babies. SANDOSTATIN LAR may harm your baby.

The safety of SANDOSTATIN LAR during pregnancy and whilst breastfeeding has not been established.

Driving and using machinery:

SANDOSTATIN LAR may cause headaches or make you feel dizzy and have an effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see 'Possible side- effects')

It is not always possible to predict to what extent SANDOSTATIN LAR may interfere with the daily activities. Therefore, you should ensure that you do not engage in the above activities until you are aware of the measure to which SANDOSTATIN LAR affects you.

SANDOSTATIN LAR contains mannitol

SANDOSTSATIN LAR contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told that you have an intolerance to some sugars, you should not be given SANDOSTATIN LAR.

3. How to receive SANDOSTATIN LAR:

You will not be expected to give yourself SANDOSTATIN LAR. It will be given to you by a person who is qualified to do so.

The usual dose is:

SANDOSTATIN LAR must always be administered as an injection into the muscle of the buttocks. With repeated administration, the left and right buttock should be used alternately.

- The starting dose is usually 20 mg SANDOSTATIN LAR, which is given at 4-week intervals.

- After about the first 3 months of treatment with SANDOSTATIN LAR, your doctor will probably want to reassess your treatment. This may involve measuring the levels of growth hormone or other hormones in your blood. Depending on these results, and on how you are feeling, the dose of SANDOSTATIN LAR may need to be changed.
- The dose given in each injection can be reduced to 10 mg or, if the treatment is not fully effective, it can be increased to 30 mg.
- If you were previously treated satisfactorily with subcutaneous SANDOSTATIN LAR, then you can immediately start treatment with SANDOSTATIN LAR as described above.
- If you were not previously treated with subcutaneous SANDOSTATIN, then you may start with a short period of subcutaneous treatment to see how you respond, before switching to SANDOSTATIN LAR.
- Depending on the particular problem for which you are being given SANDOSTATIN LAR, you may need to continue using subcutaneous SANDOSTATIN for about 2 weeks after your first injection of SANDOSTATIN LAR.

If you have the impression that the effect of SANDOSTATIN LAR is too strong or too weak, talk to your doctor or pharmacist.

How long to use SANDOSTATIN LAR

Your doctor will tell you how long your treatment with SANDOSTATIN LAR will last.
After the most suitable dose for you has been found, your doctor will probably want to reassess your treatment about every 6 months.

If you use more SANDOSTATIN LAR than you should:

Since a healthcare professional will administer SANDOSTATIN LAR, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The symptoms of overdose are: hot flushes, frequent urination, tiredness, depression, anxiety, and lack of concentration, irregular heartbeat, low blood pressure, severe upper stomach pain, yellow skin and eyes, nausea, loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, abdominal swelling or discomfort. If you think that an overdose has happened and you experience such symptoms, call your doctor.

If you missed a dose of SANDOSTATIN LAR:

Since a healthcare professional will administer SANDOSTATIN LAR, it is unlikely that the dose will be missed.

4. Possible side effects

SANDOSTATIN LAR can have side effects.

Not all side effects reported for SANDOSTATIN LAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SANDOSTATIN LAR, please consult your healthcare professional for advice.

If any of the following happens, stop taking SANDOSTATIN LAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A type of an allergic reaction (anaphylaxis),swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- hypersensitivity (allergic) reactions including skin rash or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- An inflammation of the pancreas gland (pancreatitis).
- Liver inflammation (hepatitis); symptoms may include yellowing of the skin and eyes (jaundice), nausea, vomiting, loss of appetite, generally feeling unwell, itching, light-coloured urine.
- Irregular heart beat.
- Low level of platelet count in blood; this could result in increased bleeding or bruising.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

• Diarrhoea.

• Abdominal pain.

• Nausea.

• Constipation.

• Flatulence (wind).

• Headache.

• Local pain at the injection site.

• Stomach discomfort after meal (dyspepsia).

• Vomiting.

• Feeling of fullness in the stomach.

• Fatty stools.

• Loose stools.

• Discolouration of faeces.

• Dizziness.

• Loss of appetite.

• Change in liver function tests.

• Hair loss.

• Shortness of breath.

• Gallstones, leading to sudden back pain.

• Inflammation of the gallbladder.

• Too much sugar in the blood.

• Too little sugar in the blood.

• Impaired glucose tolerance.

• Underactive thyroid gland (hypothyroidism) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck.

• Changes in thyroid function tests.

• Slow heart beat.

The following side effects have been reported less frequently:

• Thirst, low urine output, dark urine, dry flushed skin.

• Fast heart beat.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to 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 SANDOSTATIN LAR.

5. How to store SANDOSTATIN LAR

- Store at 2 °C to 8 °C (in a refrigerator).
- Keep the vial in the outer carton in order to protect it from light.
- SANDOSTATIN LAR can remain below 25 °C on the day of the injection. The suspension, however, must only be prepared immediately prior to I.M. injection.
- SANDOSTATIN LAR is a single dose vial and any unused portion must be discarded.
- Any unused product or waste material should be disposed of in accordance with local requirements.
- Store all medicines out of reach of children.
- Store in the original package/container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/carton/bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SANDOSTATIN LAR contains

- SANDOSTATIN LAR is supplied in a kit which includes one vial containing either 10, 20, or 30 mg octreotide, and one pre-filled syringe, containing 2 mL of the liquid to be used for suspending the powder (the liquid consists of sodium carboxymethylcellulose, mannitol, poloxamer 188 and sterile water)
- One vial adapter to be used for delivering the liquid from the prefilled syringe to the vial without the needle
- One 19G x 1.5” safety injection needle

The active ingredient is:

SANDOSTATIN LAR 10 mg: Each vial contains 10 mg octreotide free peptide equivalent to 11,2 mg octreotide acetate, as the active ingredient.

SANDOSTATIN LAR 20 mg: Each vial contains 20 mg octreotide free peptide equivalent to 22,4 mg octreotide acetate, as the active ingredient

SANDOSTATIN LAR 30 mg: Each vial contains 30 mg octreotide free peptide equivalent to 33,6 mg octreotide acetate, as the active ingredient.

The other ingredients are:

The powder also contains the following inactive ingredients:
poly (DL-lactide-co-glycolide) and mannitol.

SANDOSTATIN LAR SUSPENSION VEHICLE: Each prefilled syringe contains sodium carboxymethylcellulose 14 mg, mannitol 12 mg, poloxamer-188 4 mg and water for injection to make up to 2 ml.

Contains sugar: Mannitol
SANDOSTATIN LAR powder (amount per vial):
SANDOSTATIN LAR 10 mg: Mannitol 41,0 mg
SANDOSTATIN LAR 20 mg: Mannitol 81,9 mg
SANDOSTATIN LAR 30 mg: Mannitol 122,9 mg
SANDOSTATIN LAR SUSPENSION VEHICLE:
Each prefilled syringe contains mannitol 12 mg

SANDOSTATIN LAR suspension contains less than 1 mmol (23 mg) of sodium per dose, i.e. essentially ‘sodium-free’.

What SANDOSTATIN LAR looks like and contents of the pack

SANDOSTATIN® LAR® 10 mg:

White to white with yellowish tint powder in a 6 ml colourless glass vial with a grey rubber stopper and a dark blue cap.

SANDOSTATIN® LAR® 20 mg:

White to white with yellowish tint powder in a 6 ml colourless glass vial with a grey rubber stopper and an orange cap.

SANDOSTATIN® LAR® 30 mg:

White to white with yellowish tint powder in a 6 ml colourless glass vial with a grey rubber stopper and a dark red cap.

SANDOSTATIN® LAR® SUSPENSION VEHICLE:

2 ml clear, colourless to slightly yellow or brown solution glass syringe (prefilled).

Cardboard box containing:

One 6 ml glass vial with a fluroelastomer- coated rubber stopper and sealed with an aluminium flip-off seal containing microspheres for injection.

One glass prefilled syringe containing vehicle for parenteral use.

One vial adapter.

One 19G x 1.5” safety injection needle.

Holder of Certificate of Registration and Manufacturer

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This leaflet was last revised in

Date of registration: 28 August 2000

Date of revision of text: 05 September 2021

Registration numbers

SANDOSTATIN® LAR® 10 mg: 33/34/0239

SANDOSTATIN® LAR® 20 mg: 33/34/0240

SANDOSTATIN® LAR® 30 mg: 33/34/0241

SANDOSTATIN® LAR® SUSPENSION VEHICLE: 33/34/0242

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website

	Namibia		Botswana	
SANDOSTATIN® LAR® 10 mg:	08/34/0127	NS2	BOT1001717	S2
SANDOSTATIN® LAR® 20 mg:	04/34/1418	NS2	BOT1001715	S2
SANDOSTATIN® LAR® 30 mg:	08/34/0128	NS2	BOT1001714	S2
SANDOSTATIN® LAR® SUSPENSION VEHICLE	04/34/1417	NS2		