NOVARTIS

SANDOSTATIN® (octreotide acetate)

0.05 And 0.1/1 mg/ml Solution for injection or infusion

Patient Information Leaflet

Document status: Final

Approval date: 13 January 2021

SCHEDULING STATUS: S4

PRODUCT NAME

SANDOSTATIN Ampoule 0,05 mg per 1 ml

SANDOSTATIN Ampoule 0,1 mg per 1 ml

The active ingredient in SANDOSTATIN is octreotide.

Read this leaflet carefully before using SANDOSTATIN

• Keep this leaflet. You may need to read it again.

• If you have any further questions, please ask your doctor, pharmacist, nurse or other health care providers

• This medicine 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 SANDOSTATIN is and what it is used for
2. What you need to know before you are given SANDOSTATIN
3. How to use SANDOSTATIN
4. Possible side effects
5. How to store SANDOSTATIN

Contents of the pack and other information

1. WHAT SANDOSTATIN IS AND WHAT IT IS USED FOR

SANDOSTATIN Ampoule 0,05 mg per 1 ml: Each 1 ml of solution contains 0,05 mg octreotide as the active ingredient.

SANDOSTATIN Ampoule 0,1 mg per 1 ml: Each 1 ml of solution contains 0,1 mg octreotide as the active ingredient.

2. What you need to know before you are given SANDOSTATIN

SANDOSTATIN is 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.

SANDOSTATIN is used:

1. To treat acromegaly:

Acromegaly is a condition where the body produces too much growth hormone.

SANDOSTATIN is used to treat people with acromegaly:

• who are not adequately controlled by surgery or radiotherapy

• who are not fit for or unwilling to undergo surgery or

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

2. To treat SYMPTOMS in patients with carcinoid tumours:

Carcinoid tumour is a tumour which secretes large amounts of the hormone serotonin.

SANDOSTATIN is used to treat the symptoms in people with:

• carcinoid syndrome

• VIPomas (also known as Verner Morrison syndrome)

SANDOSTATIN does not cure tumours.

3. To stop bleeding:

SANDOSTATIN is used to stop bleeding and to protect from re-bleeding from ruptured gastro-oesophageal veins in patients suffering from chronic liver disease.

It is important to tell your doctor if you have other medical problems or if you are taking other medicines

You should not be given SANDOSTATIN

• If you are allergic (hypersensitive) to octreotide or any of the other ingredients of SANDOSTATIN listed at the beginning of this leaflet.

• If you are pregnant or breast-feeding your baby

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

Special care should be taken with SANDOSTATIN

If any of these apply to you, tell your doctor before you are given SANDOSTATIN

- Tell your doctor 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.
- If 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 may result in gallstone formation. Your doctor may wish to check your gallbladder periodically.
- Tell your doctor if you know that you have diabetes, as SANDOSTATIN can affect blood sugar levels. If you are diabetic, your sugar levels should be checked regularly.
- If you have a history of vitamin B12 deprivation your doctor may wish to check your B12 level periodically.
- If you receive long treatment with SANDOSTATIN your doctor may wish to check your thyroid function periodically.

Administering /being given SANDOSTATIN with food and drink

Avoid meals around the time of administration of SANDOSTATIN.

SANDOSTATIN is best injected between meals or on retiring to bed. This may reduce the gastrointestinal side effects of SANDOSTATIN.

Pregnant women

If you are pregnant or think you may be pregnant, tell your doctor. SANDOSTATIN should not be used during pregnancy. Your doctor will discuss with you the potential risks of taking SANDOSTATIN during pregnancy. Women of child-bearing potential should use an effective contraceptive method during treatment.

Breast-feeding mothers

Mothers treated with SANDOSTATIN should not breast-feed their babies. SANDOSTATIN may harm your baby.

Driving and using machines

SANDOSTATIN may cause some patients to have headaches or make them feel dizzy. If this happens, you should not drive or use machinery or perform other tasks that need full attention.

Taking other medicines with SANDOSTATIN

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of SANDOSTATIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

It is especially important that your doctor knows if you are being treated with:

• 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)

• Quinidine and terfenadine

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 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 treatment.

3. How to use SANDOSTATIN

The healthcare professional will administer your correct dose.

Depending on the condition being treated, SANDOSTATIN is given by subcutaneous (under the skin) injection or intravenous (into a vein) infusion.

Subcutaneous injection

The upper arms, thighs, and abdomen are good areas for subcutaneous injection.

Choose a new site for each subcutaneous injection so that you do not irritate a particular area.

Intravenous infusion (will be conducted by health-care professionals only)

Acromegaly

The healthcare professional will administer your correct dose.

Tumours of the gastrointestinal tract

The healthcare professional will administer your correct dose.

Bleeding gastro-oesophageal veins

The healthcare professional will administer your correct dose.

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

In the event of an overdosage

The symptoms of overdose include: 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, lack of energy, weight loss, abdominal swelling or discomfort and complete heart block. If you think that an overdose has happened and you experience such symptoms, call your doctor.

4. POSSIBLE SIDE EFFECTS

SANDOSTATIN may cause side effects.

Some side effects could be serious and might need immediate medical attention. Tell your doctor immediately if you should experience any of these side effects:

Some are frequent:

- Gallstones, leading to sudden back pain.
- Too much sugar in the blood.
- 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
- Inflammation of the gallbladder
- Too little sugar in the blood.
- Impaired glucose tolerance
- Slow heartbeat.

Some are less frequent:

- Thirst, low urine output, dark urine, dry flushed skin.
- Fast heartbeat.

Other serious side effects

If you experience any of these, tell your doctor straight away:

- Hypersensitivity (allergic) reactions including skin rash.

- A type of an allergic reaction (anaphylaxis) which can cause difficulty in swallowing or breathing, or swelling and tingling, possibly with a drop in blood pressure with dizziness or loss of consciousness.
- 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 heartbeat.
- Low level of platelet count in blood; this could result in increased bleeding or bruising.

Other side effects:

Your healthcare professional will tell you about ways to prevent or reduce some of these side- effects. Check with your healthcare professional if any of these following side effects continue or are bothersome of if you have any questions about them.

If any of these side effects affects you severely, tell your doctor.

Some are frequent:

• 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

• Hair loss

• Shortness of breath

• Weakness

Not all side effects reported for SANDOSTATIN are included in this leaflet. Should your general health worsen while taking SANDOSTATIN, please consult your doctor, pharmacist or other health care professional for advice.

5. How to store SANDOSTATIN

Keep container in the outer carton in order to protect from light.

For prolonged storage, SANDOSTATIN ampoules and multidose vials should be kept at temperatures of 2 °C to 8 °C. Do not freeze.

For day-to-day use, they may be stored at room temperature (not above 25 °C) for up to 2 weeks.

Any unused product or waste material should be disposed of in accordance with local requirements.

Keep all medicines out of the reach and sight of children.

Return any 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

SANDOSTATIN® Ampoule 0,05 mg per 1 ml: Carton of 5 ampoules of 1 ml each.

SANDOSTATIN® Ampoule 0,1 mg per 1 ml: Carton of 5 ampoules of 1 ml each.

SANDOSTATIN Ampoules also contain the following inactive ingredients lactic acid, mannitol, sodium hydrogen carbonate and water for injection.

IDENTIFICATION OF SANDOSTATIN

SANDOSTATIN® Ampoule 0,05 mg per 1 ml:

A clear, colourless solution in a 1 ml ampoule of uncoloured glass, colour coded with a blue ring and a yellow ring on the neck of the ampoule.

SANDOSTATIN® Ampoule 0,1 mg per 1 ml:

A clear, colourless solution in a 1 ml ampoule of uncoloured glass, colour coded with a blue ring and a green ring on the neck of the ampoule.

HOLDER OF CERTIFICATE OF REGISTRATION:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

Johannesburg

2090

This leaflet was last revised on:

13 January 2021

Registration number:

SANDOSTATIN® Ampoule 0,05 mg per 1 ml: V/34/230

SANDOSTATIN® Ampoule 0,1 mg per 1 ml: V/34/231

	Registration numbers			
	Namibia		Botswana	
SANDOSTATIN® Ampoule 0,05 mg per 1 ml:	90/34/00721	NS2	B9310665	S2
SANDOSTATIN® Ampoule 0,1 mg per 1 ml:	90/34/00722	NS2	B9310670	S2

Tracking number: 2020-PSB/GLC-1148-s