Package leaflet: Information for the patient

SANDOSTATIN® 50 microgram/1 mL, solution for injection/infusion
SANDOSTATIN® 100 microgram/1 mL, solution for injection/infusion
SANDOSTATIN® 500 microgram/1 mL, solution for injection/infusion

octreotide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sandostatin is and what it is used for

Sandostatin is a synthetic compound derived from somatostatin, a substance normally found in the human body which inhibits the effects of certain hormones such as growth hormone. The advantages of Sandostatin over somatostatin are that it is stronger and its effects last longer.

Sandostatin is used
- in **acromegaly**, a condition where the body produces too much growth hormone. Normally, growth hormone controls growth of tissues, organs, and bones. Too much growth hormone leads to an increase in the size of bones and tissues, especially in the hands and feet. Sandostatin markedly reduces the symptoms of acromegaly, which include headache, excessive perspiration, numbness of the hands and feet, tiredness, and joint pain.
- to relieve symptoms associated with some **tumours of the gastrointestinal tract** (e.g. carcinoid tumours, VIPomas, glucagonomas, gastrinomas, insulinomas). In these conditions, there is overproduction of some specific hormones and other related substances by the stomach, bowels, or pancreas. This overproduction upsets the natural hormonal balance of the body and results in a variety of symptoms, such as flushing, diarrhoea, low blood pressure, rash, and weight loss. Treatment with Sandostatin helps to control these symptoms.
- to prevent **complications following surgery of the pancreas gland**. Treatment with Sandostatin helps to lower the risk of complications (e.g. abscess in the abdomen, inflammation of the pancreas gland) after the surgery.
- to stop bleeding and to protect from **re-bleeding from ruptured gastro-oesophageal varices** in patients suffering from cirrhosis (chronic liver disease). Treatment with Sandostatin helps to control bleeding and reduce transfusion requirements.
- to treat pituitary tumours that produce too much thyroid-stimulating hormone (TSH). Too much thyroid-stimulating hormone (TSH) leads to hyperthyroidism.
  Sandostatin is used to treat people with pituitary tumours that produce too much thyroid-stimulating

hormone (TSH):
- when other types of treatment (surgery or radiotherapy) are not suitable or have not worked;
- after radiotherapy, to cover the interim period until the radiotherapy becomes fully effective.

2. What you need to know before you use Sandostatin

Do not use Sandostatin:
- if you are allergic to octreotide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before using Sandostatin:

- 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.

- if you have problems with your blood sugar levels, either too high (diabetes) or too low (hypoglycaemia). When Sandostatin is used to treat bleeding from gastro-oesophageal varices; monitoring of blood sugar level is mandatory.

- if you have a history of vitamin B12 deprivation your doctor may wish to check your vitamin B12 level periodically.

- Octreotide may lower your heart rate and at very high doses may cause abnormal heart rhythm. Your doctor may monitor your heart rate during treatment.

Test and checks
If you receive treatment with Sandostatin over a long period of time, your doctor may wish to check your thyroid function periodically.

Your doctor will check your liver function.

Your doctor may wish to check your pancreatic enzyme function.

Children
There is little experience with the use of Sandostatin in children.

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

You can generally continue taking other medicines while on Sandostatin. However, certain medicines, such as cimetidine, ciclosporin, bromocriptine, quinidine and terfenadine have been reported to be affected by Sandostatin.

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 your fluid and electrolyte balance, your doctor may need to adjust the dosage.

If you are diabetic, your doctor may need to adjust your insulin dosage.

If you are going to receive lutetium (^{177}Lu) oxodotreotide, a radiopharmaceutical therapy, your doctor may stop and/or adapt Sandostatin treatment.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Sandostatin should only be used during pregnancy if clearly needed.

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

Do not breast-feed while using Sandostatin. It is not known whether Sandostatin passes into breast milk.

Driving and using machines
Sandostatin has no or negligible effects on the ability to drive and use machines. However, some of the side effects you may experience while using Sandostatin, such as headache and tiredness, may reduce your ability to drive and use machines safely.

Sandostatin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

3. How to use Sandostatin

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

If you have liver cirrhosis (chronic liver disease), your doctor may need to adjust your maintenance dose.

Your doctor or nurse will explain to you how to inject Sandostatin under the skin, but infusion into a vein must always be performed by a health care professional.

- **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. Patients who will be injecting themselves must receive precise instructions from the doctor or nurse.

If you store the medicine in the refrigerator, it is recommended that you allow it to reach room temperature before using it. This will reduce the risk of pain at the site of injection. You can warm it up in your hand but do not heat it.

A few people experience pain at the site of the subcutaneous injection. This pain usually only lasts a short time. If this happens to you, you can relieve this by gently rubbing the site of injection for a few seconds afterwards.

Before using a Sandostatin ampoule, check the solution for particles or a change of colour. Do not use it if you see anything unusual.

If you use more Sandostatin than you should
The symptoms of overdose are: irregular heart beat, low blood pressure, cardiac arrest, reduced supply of oxygen to the brain, severe upper stomach pain, yellow skin and eyes, nausea, loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, abdominal swelling, discomfort, high level of lactic acid

in the blood and abnormal heart rhythm.

If you think that an overdose has happened and you experience such symptoms, tell your doctor straight away.

If you forget to use Sandostatin
Administer one dose as soon as you remember, and then continue as usual. It will not do any harm if you miss a dose, but you could get some temporary re-appearance of symptoms until you get back on schedule.

Do not inject a double dose of Sandostatin to make up for forgotten individual doses.

If you stop using Sandostatin
If you interrupt your treatment with Sandostatin your symptoms may come back. Therefore, do not stop using Sandostatin unless your doctor tells you to.

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

4. Possible side effects

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

Some side effects could be serious. Tell your doctor straight away if you get any of the following:

Very common (may affect more than 1 in 10 people):
- Gallstones, leading to sudden back pain.
- Too much sugar in the blood.

Common (may affect up to 1 in 10 people):
- 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 (cholecystitis); symptoms may include pain in the upper right abdomen, fever, nausea, yellowing of the skin and eyes (jaundice).
- Too little sugar in the blood.
- Impaired glucose tolerance.
- Slow heart beat.

Uncommon (may affect up to 1 in 100 people):
- Thirst, low urine output, dark urine, dry flushed skin.
- Fast heart beat.

Other serious side effects
- Hypersensitivity (allergic) reactions including skin rash.
- A type of an allergic reaction (anaphylaxis) which can cause difficulty in swallowing or breathing, swelling and tingling, possibly with a drop in blood pressure with dizziness or loss of consciousness.
- An inflammation of the pancreas gland (pancreatitis); symptoms may include sudden pain in the upper abdomen, nausea, vomiting, diarrhoea.
- 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.

Tell your doctor straight away if you notice any of the side effects above.

Other side effects:
Tell your doctor, pharmacist or nurse if you notice any of the side effects listed below. They are usually mild and tend to disappear as treatment progresses.

Very common (may affect more than 1 in 10 people):
- Diarrhoea.
- Abdominal pain.
- Nausea.
- Constipation.
- Flatulence (wind).
- Headache.
- Local pain at the injection site.

Common (may affect up to 1 in 10 people):
- 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.
- Weakness.

If you get any side effects, please tell your doctor, nurse or pharmacist.

A few people experience pain at the site of the subcutaneous injection. This pain usually only lasts a short time. If this happens to you, you can relieve this by gently rubbing the site of injection for a few seconds afterwards.

If you are administering Sandostatin by subcutaneous injection, it may help to reduce the risk of gastrointestinal side effects if you avoid eating meals around the time of injection. It is therefore recommended that you inject Sandostatin between meals or when you go to bed.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

Ireland
HPRA Pharmacovigilance,
Website: www.hpra.ie.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Sandostatin

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

Store in the original package in order to protect from light.

Store in a refrigerator (2°C to 8°C). Do not freeze.

The ampoules may be stored below 30°C for up to two weeks.
The ampoules should be used immediately after opening.

Diluted solutions should be used immediately after preparation.

Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice particles or a change of colour.
Do not throw away any medicines 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 pack and other information

What Sandostatin contains

- The active substance is octreotide
  Sandostatin 50 microgram: 1 ml solution contains 50 microgram octreotide.
  Sandostatin 100 microgram: 1 ml solution contains 100 microgram octreotide.
  Sandostatin 500 microgram: 1 ml solution contains 500 microgram octreotide.

- The other ingredients are lactic acid, mannitol (E421), sodium hydrogen carbonate, water for injections

What Sandostatin looks like and contents of the pack

Colourless glass ampoule with two colour code rings containing clear, colourless solution
Sandostatin 50 microgram/1 ml: one blue and one yellow
Sandostatin 100 microgram/1 ml: one blue and one green
Sandostatin 500 microgram/1 ml: one blue and one pink

Packs of three, five, six, ten, twenty and fifty ampoules.
Multipacks of ten packs, each containing three ampoules.

Not all strengths or pack sizes may be marketed in your country.

Marketing Authorisation Holder

Novartis Ireland Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

Manufacturer
Novartis Farmacéutica S.A.
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Ireland
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Malta
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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Iceland, Latvia, Lithuania, Malta, Norway, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)	Sandostatin
Belgium, France, Luxemburg, Netherlands	Sandostatine
Italy, Portugal	Sandostatina

This leaflet was last revised in 09/2021.

The following information is intended for healthcare professionals only:

- **Intravenous infusion (for health-care professionals)**

Inspect the medicinal product visually for discoloration and particulate matter prior to administration. Do not use it if you see anything unusual. For intravenous infusion dilute the product prior to administration. Sandostatin (octreotide acetate) is physically and chemically stable for 24 hours in sterile physiological saline solutions or sterile solutions of dextrose (glucose) 5% in water. However, because Sandostatin can affect glucose homeostasis, it is recommended that physiological saline solutions be used rather than dextrose. The diluted solutions are physically and chemically stable for at least 24 hours below 25°C. From a microbiological point of view, the diluted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
The contents of one 500 micrograms ampoule should normally be dissolved in 60 mL physiological saline, and the resulting solution should be infused by means of an infusion pump. This should be repeated as often as necessary until the prescribed duration of treatment is reached.

How much Sandostatin to use

The dose of Sandostatin depends on the condition being treated.

- **Acromegaly**

Treatment is usually started at 0.05 to 0.1 mg every 8 or 12 hours by subcutaneous injection. It is then changed according to its effect and relief of symptoms (such as tiredness, sweating and headache). In most

patients the optimal daily dose will be 0.1 mg 3 times/day. A maximum dose of 1.5 mg/day should not be exceeded.

- **Tumours of the gastrointestinal tract**

Treatment is usually started at 0.05 mg once or twice a day by subcutaneous injection. Depending on response and tolerability, the dosage can be gradually increased to 0.1 mg to 0.2 mg 3 times/day. In carcinoid tumours, therapy should be discontinued if there is no improvement after 1 week of treatment at the maximum tolerated dose.

- **Complications following pancreatic surgery**

The usual dosage is 0.1 mg 3 times/day by subcutaneous injection for 1 week, starting at least 1 hour before surgery.

- **Bleeding gastro-oesophageal varices**

The recommended dosage is 25 micrograms/hour for 5 days by continuous intravenous infusion. Monitoring of blood sugar level is necessary during treatment.

- **TSH-secreting pituitary adenomas**

The dosage most generally effective is 100 micrograms three times a day by subcutaneous injection. The dose can be adjusted according to the responses of TSH and thyroid hormones. At least 5 days of treatment will be needed to judge the efficacy.