SANDOSTATIN® SOLUTION FOR INJECTION/ INFUSION

Octreotide Acetate (0.05mg/1ml, 0.1 mg/1ml)

What is in this leaflet

What Sandostatin is used for

Sandostatin is used

- to treat 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. By decreasing the growth hormone levels, 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 tumors, VIPomas, glucagonomas, gastrinomas, insulinomas, GRFomas). 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 chance 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 individual suffering from cirrhosis (chronic liver disease). Treatment with Sandostatin helps to control bleeding and reduce transfusion requirements.

How Sandostatin works

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.

Before you use Sandostatin

Follow all instructions given to you by your doctor carefully. They may differ from the general information contained in this leaflet.
Read the following explanations before you use Sandostatin.

- *When you must not use it*

If you are hypersensitive (allergic) to octreotide or any of the other ingredients of Sandostatin listed in this leaflet.

Pregnant and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will discuss with you the potential risk of taking Sandostatin during pregnancy.

- Sandostatin should only be used during pregnancy if clearly needed. Tell your doctor if you are pregnant, or want to become pregnant.
- It is not known if Sandostatin passes into breast milk.

Nevertheless, you should not breast-feed your child while using Sandostatin.

Women of child-bearing potential

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

- *Before you start to use it*

- 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.
- 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 B_{12} deprivation your doctor may wish to check your B_{12} level periodically.
- If you receive long treatment with Sandostatin your doctor may wish to check your Thyroid function periodically.

Taking Sandostatin with food

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.

Children and adolescents (below 18 years)

Sandostatin can be given to children, but experience in children is limited.

Older people (65 years or above)

Experience with Sandostatin has shown that there are no special requirements for elderly of 65 years old and over.

- *Taking other medicines (Interactions with other medicinal products including vaccines or biologics)*

Sandostatin may interfere with some other medicines. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
You can generally continue taking other medicines while on Sandostatin. However, certain medicines such as cimetidine, ciclosporin, bromocriptine, quinidine and terfenadine can 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 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.

How to use Sandostatin
Depending on the condition being treated, Sandostatin is given by subcutaneous (under the skin) injection or intravenous (into a vein) infusion. Your doctor or nurse will explain 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. If you will be injecting yourself, you must receive precise directions from the doctor or the nurse.
To reduce pain at the site of the injection, it is recommended that, if kept in the refrigerator, the ampoule should be allowed to reach room temperature. You can warm it up in your hand but do not heat it.

Intravenous infusion
To be performed by healthcare professionals.

- *How much and when to use*

- 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 people, 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 daily 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 operation.

- Bleeding gastro-oesophageal varices

The recommended dosage is 25 microgram/hour for 5 days by continuous intravenous infusion. Monitoring of blood sugar level is necessary during treatment. If you have liver cirrhosis (chronic liver disease), your doctor may need to adjust your maintenance dose.
If you have the impression that the effect of Sandostatin is too strong or too weak, talk to your doctor or pharmacist.

- *How long to use Sandostatin*

Continue taking Sandostatin for as long as your doctor recommends.

- *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 take a double dose to make up for forgotten individual doses.

- *If you use too much (overdose)*

The symptoms of overdose may include irregular heartbeat, low blood pressure, heart attack, brain lack of oxygen, severe upper stomach pain, yellow skin and eyes, nausea, loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, abdominal swelling, discomfort, lactic acidosis and complete heart block.
If you think that an overdose has happened and you experience such symptoms, call your doctor.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor or pharmacist.
Do not give Sandostatin to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines
There is no information on the effects of Sandostatin on your ability to drive and use machines.

Side effects
As with all medicines, treatment with Sandostatin may experience some side effects, although not everybody gets them. If you experience any of these, tell your doctor.

A few people experience pain at the injection site of the subcutaneous injection, which is usually of short duration. If this occurs, you can relieve it by gently rubbing the site of injection for a few seconds afterwards.
The above undesirable effects may be reduced by injecting Sandostatin between meals or on retiring to bed.

Some side effects could be serious and might need immediate medical attention

Some side effects are very common:
(These side effects may affect more than 1 in 10 people)

- Gallstones, leading to sudden back pain.
- Too much sugar in the blood.

Some side effects are common:
(These side effects may affect between 1 and 10 in every 100 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).
- Too little sugar in the blood.
- Impaired glucose tolerance.
- Slow heartbeat.

Some side effects are uncommon:
(These side effects may affect between 1 and 10 in every 1,000 people)
- 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, 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:
The side effects listed below are usually mild and tend to disappear as treatment progresses.

Some side effects are very common:
(These side effects may affect more than 1 in 10 people)
- Diarrhoea.
- Abdominal pain.
- Nausea.
- Constipation.
- Flatulence (wind).
- Headache.
- Local pain at the injection site.

Some side effects are common:
(These side effects affect between 1 and 10 in every 100 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 experience any other side effects that is not mentioned in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Sandostatin
- *Storage*
- Do not use Sandostatin after the expiry date.
- When stored for a long period of time, Sandostatin ampoules must be kept at 2℃ to 8°C (in a refrigerator). Keep the container in the outer carton in order to protect from light.
- Do not freeze.
- For day-to-day use, Sandostatin ampoules may be stored not above 30°C for up to 2 weeks.
- Store in the original package.
- Keep out of the reach and sight of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
- *What it looks like*

Sandostatin is supplied as 0.05 mg/1 mL and 0.1 mg/1 mL ampoules. The pharmaceutical form is a solution for injection (s.c) or concentrate for solution for infusion (i.v. infusion). The solution is clear and colourless. This information might differ in some countries.

- *Ingredients*
- Active ingredients
- The active substance is octreotide acetate.
- 1 mL ampoules containing 0.05 or 0.1 mg octreotide.

- *Inactive ingredients*

Ampoules
- Lactic acid, mannitol, sodium hydrogen carbonate, and water for injection.

- *MAL Number*

Sandostatin 0.05mg/1ml : MAL19913234ARZ

Sandostatin 0.1mg/1ml : MAL19913235ARZ

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Novartis Pharma Stein AG, Stein, Switzerland

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