

Sandostatin[®]

octreotide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sandostatin.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Sandostatin against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Sandostatin is used for

Sandostatin has three uses:

1. Sandostatin is used to treat acromegaly

In people with acromegaly the body makes too much growth hormone, which controls the growth of tissues, organs and bones. This leads to enlargement of the bones, especially of the hands and feet. Other symptoms include headaches, increased sweating, tiredness, numbness of the hands and feet, pain and stiffness in the joints and loss of sexual function. By blocking the excess growth hormone, Sandostatin can relieve many of these symptoms.

2. Sandostatin is used to relieve symptoms of certain types of cancer such as carcinoid syndrome and VIPoma.

By blocking hormones that are over-produced in these conditions, Sandostatin can relieve symptoms such as flushing of the skin and severe diarrhoea.

3. Sandostatin is used for people who are having surgery on the pancreas. This medicine helps to lower the chance of complications after the surgery.

Sandostatin contains octreotide, a man-made medicine derived from somatostatin, a substance found in the human body.

Octreotide is used instead of somatostatin because its effects are stronger and last longer so that it needs to be given only 2 or 3 times a day.

Ask your doctor if you have any questions about why Sandostatin has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is only available with a doctor's prescription. It is not addictive.

There is very little information on the use of this medicine in children.

Before you use Sandostatin

When you must not use it

Do not use Sandostatin if you have an allergy to:

- octreotide (the active ingredient in Sandostatin) or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Sandostatin after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have, or have had, any of the following medical conditions:

- gallstones currently or in the past or experience any complications like fever, chills, abdominal pain, or yellowing of your skin or eyes as prolonged use of Sandostatin may result in gallstone formation
- diabetes, as Sandostatin can affect blood sugar levels. If you are diabetic, your sugar levels should be checked regularly
- problems with your liver
- a history of vitamin B12 deprivation.

Your doctor may want to take special precautions if you have any of the above conditions.

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 adjustment may be necessary.

Tell your doctor if you are pregnant or intend to become pregnant or wish to breast-feed your baby.

There is not much information on the use of Sandostatin during pregnancy or breast-feeding. If it is necessary for you

to use this medicine, your doctor will discuss with you the benefits and risks involved. They may recommend that you use a method of contraception to prevent pregnancy during your treatment. It is not known if Sandostatin passes into breast milk. Breastfeeding is not recommended during treatment with Sandostatin.

If you have not told your doctor about any of these things, tell him/her before you use Sandostatin.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Sandostatin may interfere with each other. Some of these medicines include:

- bromocriptine, a medicine which is also used to treat acromegaly
- medicines for diabetes
- cimetidine, a medicine for ulcers
- cyclosporin, a medicine used to suppress the immune system
- quinidine, a medicine used to prevent irregular heartbeats
- medicines to control blood pressure (beta-blockers or calcium channel blockers)

- agents to control fluid and electrolyte balance

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Sandostatin.

How to use Sandostatin

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How it is given

Sandostatin cannot be taken by mouth because it is rapidly broken down in the stomach. Instead it is given as a subcutaneous injection. That means that it is injected into the fat layer just under the skin.

How much is given

The dose of Sandostatin depends on the condition being treated.

1. Acromegaly: treatment is usually started with injections of 0.05 to 0.1 mg every 8 or 12 hours. The dose can then be

adjusted depending on how well it blocks growth hormone and relieves symptoms such as tiredness, sweating and headache.

2. Carcinoid syndrome and VIPoma: treatment is usually started with injections of 0.05 mg once or twice a day. The dose can be increased if symptoms such as diarrhoea are not relieved.
3. Surgery on the pancreas: injections of 0.1 mg are usually given three times a day for one week, starting about an hour before the operation.

If you are giving the injections yourself

If you will be giving the injections yourself, your doctor or nurse will teach you how to do it properly.

Before using a Sandostatin ampoule, check the liquid for particles or a change in colour. If you notice anything unusual, do not use the ampoule.

Once an ampoule is opened, use it immediately and throw out any liquid that remains.

Single use. Contains no antimicrobial agent.

Give the injections between meals or at bedtime. Avoid having meals around the time of the injections.

This will help to reduce the chance of stomach upset.

To help prevent irritation or pain at the injection site:

- Choose a new site for each injection. The upper arms, thighs and abdomen are good areas for injection.
- Make sure the ampoule is at room temperature before you use it. If it has been in the fridge, take it out half an hour before using it. You can warm it up in your hand but don't try to heat it.

If you notice pain, stinging, tingling, burning, redness or swelling at the injection site after the injection, gently rub the site for a few seconds.

These side effects rarely last more than 15 minutes after an injection.

If you forget to use it

Inject the dose as soon as you remember, and then go back to using it as you would normally.

It won't do any harm if you miss a dose but some of your symptoms may come back temporarily until you get back on schedule.

Do not use a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that an overdose has happened. Do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of an overdose may include irregular heart beat, low blood pressure, cardiac arrest, brain hypoxia, 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.

No life-threatening reactions have been reported after an overdose of this medicine.

While you are using Sandostatin

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

If you must use this medicine for a long time, your doctor may want to check your blood sugar, gallbladder, thyroid and liver function from time to time to prevent unwanted side effects from happening.

If your doctor recommends it, make sure you use a method of contraception to prevent pregnancy during your

treatment. Tell your doctor if you become pregnant while you are receiving this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Sandostatin.

Tell any other doctor, dentist or pharmacist who treats you that you are using Sandostatin.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Sandostatin affects you.

This medicine may cause dizziness, lightheadedness or weakness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Sandostatin.

All medicines can cause side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing
- severe pain, tenderness or swelling in the stomach or abdomen, which may be accompanied by fever, nausea and vomiting, yellowing of the skin and eyes, loss of appetite, generally feeling unwell, itching, light coloured urine (symptoms of a possible problem with your liver, pancreas or gall bladder)
- symptoms of low blood glucose (hypoglycaemia), including sweating, trembling, dizziness, weakness, hunger, palpitations (feeling of fast or irregular heartbeat) and fatigue
- symptoms of high blood glucose (hyperglycaemia), including lethargy or tiredness, headache, thirst, passing large amounts of urine, and blurred vision

- unusually slow or fast heartbeat
- increased bleeding or bruising (could be low level of platelets in blood).

Tell your doctor if you notice any of the following side effects and they worry you:

- pain, irritation, redness, rash or swelling at the injection site
- loss of appetite
- indigestion, nausea or vomiting
- cramps
- feeling of bloating or wind
- constipation, diarrhoea or other change in bowel motions
- headache
- dizziness or light headedness
- swelling of hands or feet due to excess fluid
- tiredness or weakness
- flushing of the skin
- temporary hair loss
- changes in the rhythm of your heartbeat

- shortness of breath
- symptoms of changes in the activity of the thyroid gland (hyper or hypothyroidism) including changes in heart rate, appetites or weight, tiredness, feeling cold or sweating too much, anxiety or swelling at the front of the neck.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using Sandostatin

Storage

- Keep the ampoules in the original container until it is time to use them.
- You can store the ampoules for up to 2 weeks at room temperature.
- If you are storing the ampoules for longer than 2 weeks, keep them in the refrigerator. Do not freeze them.
- Do not store Sandostatin or any other medicine in the bathroom or near a sink.
- Do not leave them in the car or on window sills.

Keep the medicine where children cannot reach it.

Disposal

If any ampoules have been left out of the fridge for longer than 2 weeks, do not use them.

If your doctor tells you to stop using this medicine or you find that the expiry date has passed or the ampoules have been left out of the fridge for too long, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Sandostatin solution for injection is a clear and colourless liquid supplied in boxes of 5 ampoules. The solution is filled into a 1 mL colourless glass ampoule with two colour code rings and a one-point cut.

Ingredients

Sandostatin ampoules contain 0.05 mg, 0.1 mg or 0.5 mg of the active ingredient, octreotide (as octreotide acetate). They also contain:

- lactic acid
- mannitol
- sodium bicarbonate

- water for injections

Sponsor

Sandostatin is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

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This leaflet was prepared in September 2021

Australian Registration Number.

Sandostatin 0.05 mg ampoule

AUST R 42192

Sandostatin 0.1 mg ampoule

AUST R 42193

Sandostatin 0.5 mg ampoule

AUST R 42191

For internal use only

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