

SANDOSTATIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SANDOSTATIN?

SANDOSTATIN contains the active ingredient octreotide. SANDOSTATIN is used to block the production of excessive growth hormone and acts to reduce the amount of other chemicals and proteins that occur naturally in your body. This may be useful in treating certain types of cancers, excessive body part growth (acromegaly) and following surgery on your pancreas. For more information, see Section [1. Why am I using SANDOSTATIN?](#) in the full CMI.

2. What should I know before I use SANDOSTATIN?

Do not use if you have ever had an allergic reaction to SANDOSTATIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions such as problems with your liver, gall bladder, heart, or blood sugar. Tell your doctor if

you take any other medicines or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section [2. What should I know before I use SANDOSTATIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SANDOSTATIN and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SANDOSTATIN?

- SANDOSTATIN is given by injection under the skin using special equipment designed to use the glass capsule (ampoule)
- You may be able to take SANDOSTATIN at home, your doctor or nurse will show you how to do this and provide you with this equipment.

More instructions can be found in Section [4. How do I use SANDOSTATIN?](#) in the full CMI.

5. What should I know while using SANDOSTATIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, surgeon, pharmacist, or
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	<p>anesthetist that you are using SANDOSTATIN.</p> <ul style="list-style-type: none"> • Attend any follow-up appointments to check how you are responding to treatment. • Take contraception (birth control) if your doctor tells you to in order to avoid becoming pregnant.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not give this medicine to someone else.
Driving or using machines	<ul style="list-style-type: none"> • SANDOSTATIN may make you feel dizzy, light-headed, or weak. Do not drive or do anything else that would require your attention.
Drinking alcohol	<ul style="list-style-type: none"> • SANDOSTATIN may make you feel dizzy, light-headed, or weak. You should avoid alcohol while on treatment with SANDOSTATIN.

Looking after your medicine	<ul style="list-style-type: none"> • SANDOSTATIN should generally be kept in the fridge (set between 2 - 8°C). Do NOT freeze it. • SANDOSTATIN can also be stored for up to 2 weeks at room temperature (below 30°C) for daily use. If the ampoules have not been kept in the fridge for more than 2 weeks, throw them away.
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For more information, see Section [5. What should I know while using SANDOSTATIN?](#) in the full CMI.

6. Are there any side effects?

Some common side effects include diarrhoea, constipation, feeling gassy, stomach pain/discomfort or cramps, feeling or being sick, headaches, dizziness, gall stones, weight changes, high blood sugar, redness, itchiness, swelling or rash at injection site, redness elsewhere on the skin, hair loss, feeling tired, weak, anxious, or cold. Serious side effects include signs of an allergic reaction including 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; severe stomach pain, tenderness or swelling; signs of liver disease including yellowing of skin or whites around eyes; changes to vision; passing much less

urine or unable to pass urine when going to the toilet; trembling hands or balance problems; sweating more than normal; feeling faint/rapid heartbeat; bruising more than normal.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SANDOSTATIN[®] (San-do-statin)

Active ingredient(s): *Octreotide* (ok-TREE-oh-tide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SANDOSTATIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SANDOSTATIN.**

Where to find information in this leaflet:

- [1. Why am I using SANDOSTATIN?](#)
- [2. What should I know before I use SANDOSTATIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SANDOSTATIN?](#)
- [5. What should I know while using SANDOSTATIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SANDOSTATIN?

SANDOSTATIN contains the active ingredient octreotide. SANDOSTATIN is an anti-growth hormone, meaning that it is used to block the production of excessive growth hormone that occurs naturally in your body. It also works to reduce the amount of other

chemicals and proteins in your body that may be making you unwell.

SANDOSTATIN has three main uses.

- 1. Treatment of acromegaly. This is a condition where the body produces too much hormone that controls the growth of your bones, organs, and tissues. SANDOSTATIN helps reduce the amount of this chemical in your body to relieve the effects of this condition which may include stiffness or pain in your joints and larger than normal bones in your hand and feet.**
- 2. Relieve the effects of some types of cancer (uncontrolled cell growth) including carcinoid syndrome (tumour of the gut/lungs) and VIPoma (tumour of the gut) such as diarrhoea.**
- 3. In people who are having surgery on their pancreas to help reduce the chance of having problems after the surgery.**

2. What should I know before I use SANDOSTATIN?

Warnings

Do not use SANDOSTATIN if:

- you are allergic to octreotide, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have previously had or currently have gallstones
- have previously had or currently have diabetes
- have previously had or currently have liver problems
- have previously had or currently have low vitamin B12
- are taking medication to treat high blood pressure
- are taking medication to manage fluid retention/
electrolytes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Monitoring

Before commencing treatment, your doctor may send you for blood/urine tests. They may refer you to specialist appointments to check on your gall bladder, thyroid, or liver function. They may also monitor you throughout treatment to see how your body is responding and whether your dose may need to change.

Some tests, such as blood sugar, you may also be required to do which can be done from home.

Gallstones

Using SANDOSTATIN, especially if you must use it for a long time may cause gallstones. Your doctor will want to know if you have gallstones currently or have experienced things like fever, chills, stomach pain, or a yellowing of the skin/eyes because of gallstones in the past. Your doctor will likely send you for an ultrasound of the gallbladder before treatment and throughout treatment.

Diabetes

SANDOSTATIN can affect your blood sugar. If you are a diabetic or may be at risk of developing diabetes, your doctor may want to closely monitor your blood sugar levels using special equipment. If you are currently taking insulin, your doctor may alter your dose.

Liver function

If you have liver scarring or problems with your liver, your doctor may adjust your dose. Your body may take more time than expected to handle the medicine for each dose.

Nutrition

Your doctor may want to check your vitamin B12 levels in your blood. SANDOSTATIN may also change how your body handles fat in your diet. Your doctor may refer you to a dietician.

Heart function and blood pressure

Your doctor may change your dose of SANDOSTATIN if you are taking medicines to control blood pressure or electrolytes.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think you may be pregnant or intend to become pregnant. There is limited information on using SANDOSTATIN while pregnant or when trying to have a baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether SANDOSTATIN passes through breast milk and may harm your baby.

Contraception

Your doctor may request that you take an effective contraception (birth control) to prevent pregnancy.

Children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with SANDOSTATIN and affect how it works. These can include:

- Medicines to control your blood pressure (e.g., beta-blockers)
- Medicines to control fluid retention or electrolytes (e.g., calcium blockers)
- Medicines to treat heartburn/stomach ulcer (e.g., cimetidine)
- Medicines used following transplant (e.g., cyclosporin)
- Medicines used to treat pituitary gland tumours (e.g., bromocriptine)
- Medicines used to treat irregular heartbeat (e.g., quinidine)
- Medicines used to manage blood sugar (e.g., Insulin)

For you to more safely use SANDOSTATIN, your doctor may alter your dose of SANDOSTATIN or your other medications depending on what you are taking.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SANDOSTATIN.

4. How do I use SANDOSTATIN?

How to use SANDOSTATIN

- SANDOSTATIN is injected just under the skin. See section "How to inject SANDOSTATIN"
- Your doctor will tell you how much SANDOSTATIN to take based on your condition and whether you may be taking other medications/have any other health conditions.
- Follow the instructions provided and use SANDOSTATIN until your doctor tells you to stop.
- If you do not understand how to use it properly and you are injecting it at home, ask your doctor for help.
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How much to use

If you have acromegaly

- Your doctor will usually start you on injections of between 0.05 to 0.1 mg taken every 8 or 12 hours.
- Your doctor may adjust your dose depending on how well your body responds to treatment.

If you have Carcinoid syndrome and VIPoma

- Your doctor will usually start you on injections of 0.05 mg once or twice a day.
- Your doctor may adjust your dose depending on how well your body responds to treatment.

If you have recently had surgery on your pancreas

- Your doctor will usually start you on injections of 0.1 mg usually given three times a day for one week, starting about an hour before the operation.
- Your doctor may adjust your dose depending on how well your body responds to treatment.

When to use SANDOSTATIN

- SANDOSTATIN should be injected in between meals or at bedtime. Avoid having a meal close to when you are injecting as it may upset your stomach.

Before you inject SANDOSTATIN at home

- Your doctor or nurse will show you how to do this. It is important that you can do this when they send you home with it.
- 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 in the microwave.
- Check the liquid in the glass capsule (ampoule) - it should be clear and colourless.
- You must not take SANDOSTATIN if the capsules show floating pieces (particles), or the liquid is discoloured (see section "Getting rid of unwanted medicine").

Injecting SANDOSTATIN at home

- Inject SANDOSTATIN the same way your doctor or nurse has shown you with the equipment they provide you.
- Choose a new site each time you need to inject (avoid injecting in the same place during back-to-back treatments).
- The upper arms, thighs and abdomen are good areas for injection.

After you receive your injection of SANDOSTATIN

- Throw away the glass capsule (ampoule) that was used. Each capsule may only be used once.
- 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. If it persists into the day and it worries you, talk to your doctor.

If you forget to use SANDOSTATIN

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

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted effect.

If you use too much SANDOSTATIN

If you think that you have used too much SANDOSTATIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of taking too much SANDOSTATIN may include irregular heartbeat, low blood pressure, cardiac arrest, brain hypoxia (lower level of oxygen than normal going to your brain), severe upper stomach pain, yellow skin, and eyes, feeling sick/vomiting, loss of appetite, diarrhoea, weakness, tiredness, lack of energy, weight loss, abdominal swelling, discomfort, painful muscle cramps and changes to heart rhythm.

5. What should I know while using SANDOSTATIN?

Things you should do

- Keep all your appointments, including those for specialists so that your overall health and response to treatment can be monitored.
- Complete blood/urine tests requested by your doctor promptly.
- Ensure you take an effective form of contraception if your doctor asks you to.

Call your doctor straight away if you:

- You are pregnant or think you may be pregnant.

Remind any doctor, dentist, surgeon, anaesthetist, or pharmacist you visit that you are using SANDOSTATIN.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give this medicine to someone else.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SANDOSTATIN affects you.

SANDOSTATIN may make you feel dizzy, light-headed, or weak. Do not drive or do anything else that would require your attention.

Drinking alcohol

Tell your doctor if you drink alcohol.

SANDOSTATIN may make you feel dizzy, light-headed, or weak. You should avoid alcohol while on treatment with SANDOSTATIN.

Looking after your medicine

Keep the ampoules (glass capsules) in their original container inside the carton until it is time to use them. Follow the instructions in the carton on how to take care of your medicine properly.

You should store SANDOSTATIN in the fridge (set between 2 - 8°C). Do NOT freeze it.

SANDOSTATIN can also be stored for up to 2 weeks at room temperature (below 30°C) for day-to-day use. Any ampoules that have not been used within this time must be thrown away if they have not been kept in the fridge.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

- if the pack has been out of the fridge for more than 2 weeks, take it to a pharmacy for disposal.
- if there is any leftover from the glass capsule after you have opened it and taken the injection, it can be thrown away.

Getting rid of any unwanted medicine

- If your glass capsules (ampoules) are discolored or have floating pieces (particles) in it, take it to your pharmacist to exchange it.
- If your doctor tells you that you no longer need to use this medicine or it is out of date, damaged or shows signs of tampering, take it to any pharmacy for safe disposal.
- Do not use this medicine after the expiry date or if you have not kept it in the fridge for more than 2 weeks. Take it to a pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Skin problems</p> <ul style="list-style-type: none"> • Swelling, redness, rash, swelling or itching at the site of injection. • Flushing (redness) of the skin elsewhere. <p>Stomach problems</p> <ul style="list-style-type: none"> • Indigestion, cramps, discomfort • Bloating, wind • Constipation/diarrhoea • Loss of appetite <p>General wellbeing</p> <ul style="list-style-type: none"> • Feeling sick, vomiting • Headache • Feeling dizzy or lightheaded • Feeling tired or weak <p>Mood and body changes</p> <ul style="list-style-type: none"> • Faster heart rate • Change in weight • Feeling cold • Increased sweating 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Tell your doctor if anything is making you feel unwell.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Feeling anxious • Swelling of hands or feet from fluid. • Thyroid changes • Temporary hair loss 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction</p> <ul style="list-style-type: none"> • Sudden onset of rash, hives, itching, blisters that are spreading • Swelling of the face, lips and tongue or other parts of the body • Wheezing, difficulty breathing, unable to catch your breath. <p>Stomach problems</p> <ul style="list-style-type: none"> • Severe stomach pain, swelling, tenderness. <p>Liver problems</p> <ul style="list-style-type: none"> • Yellow skin and eyes, feeling generally unwell 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may require medical treatment.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Fever accompanied by feeling sick or vomiting <p>Kidney problems</p> <ul style="list-style-type: none"> • Yellow skin and eyes, feeling generally unwell <p>Blood sugar/pancreas problems</p> <ul style="list-style-type: none"> • Sweating more than normal, feeling weak, tired, or trembling. • Feeling dizzy, weak, hungry • Fast or irregular heartbeat • Passing large amounts of urine that is discolored/feeling very thirsty. • Changes to vision <p>Blood problems</p> <ul style="list-style-type: none"> • Bruising more easily than normal • Increased bleeding from wound 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription. SANDOSTATIN ampoules contain 0.05 mg, 0.1 mg or 0.5 mg of the active ingredient, octreotide (as octreotide acetate).

What SANDOSTATIN contains

Active ingredient (main ingredient)	Octreotide (as octreotide acetate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactic acid• mannitol• sodium bicarbonate

	• water for injections
Potential allergens	-

Do not take this medicine if you are allergic to any of these ingredients.

What SANDOSTATIN looks like

SANDOSTATIN solution for injection is a clear and colourless liquid. The solution is filled into a 1 mL colourless glass ampoule (glass capsule) with two colour coded rings and a one-point cut.

SANDOSTATIN solution for injection is available in three strengths in boxes that contain 5 ampoules:

- 0.05 mg ampoules, box of 5 (AUST R 42192)
- 0.1 mg ampoules, box of 5 (AUST R 42193)
- 0.5 mg ampoules, box of 5 (AUST R 42191)

Who distributes SANDOSTATIN

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Macquarie Park NSW 2113

Telephone 1800 671 203

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