

SANDOSTATIN LAR®

Consumer Medicine Information (CMI) summary

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

1. Why am I receiving SANDOSTATIN LAR?

SANDOSTATIN LAR contains the active ingredient octreotide. SANDOSTATIN LAR is used to treat a few conditions including acromegaly, advanced neuroendocrine tumours of the gut, and the symptoms of carcinoid tumour and VIPoma. For more information, see Section [1. Why am I receiving SANDOSTATIN LAR?](#) in the full CMI.

2. What should I know before I receive SANDOSTATIN LAR?

Do not use if you have ever had an allergic reaction to SANDOSTATIN LAR (octreotide) or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

SANDOSTATIN LAR is not recommended in these situations. For more information, see Section [2. What should I know before I receive SANDOSTATIN LAR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SANDOSTATIN LAR 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 receive SANDOSTATIN LAR?

- SANDOSTATIN LAR must only be administered by a doctor or other healthcare professional and only into the muscles of your buttocks. The side you receive SANDOSTATIN LAR will alternate from left to right on each visit you have.
- SANDOSTATIN LAR requires a healthcare professional to prepare your dose correctly.

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

5. What should I know while I am receiving SANDOSTATIN LAR?

Things you should do	<ul style="list-style-type: none">• Keep all your doctor's appointments so that your progress and
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	<p>overall health can be checked.</p> <ul style="list-style-type: none"> ● Use contraception (birth control) to avoid becoming pregnant.
Things you should not do	<ul style="list-style-type: none"> ● Do not use SANDOSTATIN LAR if it has been kept out of the fridge for more than 24 hours. ● Do not give this medicine to someone else. ● Do not prepare or inject SANDOSTATIN LAR yourself. Your doctor will do this.
Driving or using machines	<ul style="list-style-type: none"> ● Be careful driving or using machines. May cause dizziness, lightheadedness, or weakness.
Drinking alcohol	<ul style="list-style-type: none"> ● Tell your doctor if you drink alcohol. May cause dizziness or lightheadedness. Alcohol may make this worse.

Looking after your medicine

- Keep the vials in the carton until it is time to use them to protect them from light.
- Keep them in the carton, in the refrigerator at 2°C to 8°C. Do not freeze them.
- You may remove the carton from the refrigerator on a day you have an injection scheduled. Do not keep them out of the fridge for longer than 24 hours, otherwise it is not safe to use them.

For more information, see Section [5. What should I know while I am receiving SANDOSTATIN LAR?](#) in the full CMI.

6. Are there any side effects?

More common side effects include Feeling sick, tired, or weak, vomiting, diarrhoea/loose stools, discoloured stools, constipation, abdominal pain, cramps, feeling bloated or gassy, indigestion, headache, dizziness, weight changes, redness, swelling or itching at the injection site, rash, hair loss. More serious side effects include signs of an allergic reaction such as trouble breathing, wheezing, swelling of the tongue, lips or face;

hives or rash that is spreading, bruising more easily, more bleeding than normal, gall stones, changes to blood sugar (too high, too low), body temperature shifts (too hot, too cold), severe abdominal pain or swelling, yellowing of skin or eyes, trembling, blurred vision, passing very dark urine or little urine, rapid heart rate (palpitations). 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 LAR (San-do-statin L.A.R)

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I receiving SANDOSTATIN LAR?

SANDOSTATIN LAR contains the active ingredient octreotide.

SANDOSTATIN LAR is an anti-growth hormone agent, meaning it stops the production of hormones. Sandostatin is derived from somatostatin. Somatostatin is a substance found in the human body which controls the effects of certain hormones such as insulin and growth hormone. SANDOSTATIN LAR is used instead of somatostatin because its effects are stronger and last longer.

SANDOSTATIN LAR is injected into the muscles of your buttocks generally every four weeks by a doctor or healthcare professional; instead of having to inject short-acting Sandostatin more frequently under the skin.

SANDOSTATIN LAR is used to treat the following conditions:

Acromegaly

A condition where the body makes too much growth hormone causing you to have bigger hands and feet than normal. While growth hormone in the body is important as it controls the growth of your organs and body tissues, it may also cause lots of sweating, headaches, stiff joints, loss of feeling in hands and feet and sexual dysfunction if you have too much.

SANDOSTATIN LAR reduces the amount of hormones in your body and may be given to you when other types of treatment for acromegaly (such as surgery or radiotherapy) are not suitable or haven't worked. SANDOSTATIN LAR may also be given to you AFTER radiotherapy, to cover the interim period until the radiotherapy becomes fully effective.

Relieve the symptoms of certain types of cancer - carcinoid tumour and VIPoma

Carcinoid tumours are a type of slow-growing tumour that can start in several places in the body. VIPoma however is a type of tumour that generally starts in the pancreas (the organ that produces insulin). By blocking hormones that are over-produced in these conditions, SANDOSTATIN LAR can relieve symptoms of these tumours such as flushing of the skin and severe diarrhoea.

Advanced Neuroendocrine Tumours

Neuroendocrine cells receive signals from the nervous system (like nerve cells) and respond to this by making hormones (like endocrine cells).

Neuroendocrine tumours can be found in different parts of the body, however SANDOSTATIN LAR treats rare tumours located in the gut (e.g. small intestine, colon, or appendix) by blocking these hormones and controlling the growth.

2. What should I know before I receive SANDOSTATIN LAR?

Warnings

Do not receive SANDOSTATIN LAR 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 receive this medicine. 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.

Check with your doctor if you have/have had:

- gallstones
- problems with your liver
- diabetes or problems with blood sugar being too high or too low
- low vitamin B12
- blood pressure issues
- problems with your thyroid
- problems with your pancreas
- any medicines for any other condition

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 while on treatment

If you are going to be receiving SANDOSTATIN LAR for a while, your doctor may want to monitor your blood sugar, gallbladder, thyroid, and liver function from time to time to prevent unwanted side effects from happening.

Your doctor may also want to monitor your pancreas function, especially if you are taking other medicines to control your blood sugar.

Your doctor may send you for blood tests to monitor your liver enzymes, hormones, and vitamin B12 as well.

Gallstones

Your doctor will want to know if you have experienced any complications like fever, chills, abdominal pain, or yellowing of your skin or eyes as prolonged use of SANDOSTATIN LAR may result in gallstone formation.

Taking other medicines

Your doctor will want to know if you are taking medicines to control blood pressure (beta-blockers or calcium channel blockers) or agents to control fluid and electrolyte balance. They may change your dose or treatment plan based on this.

Children

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

Contraception

You should avoid becoming pregnant while you are receiving SANDOSTATIN LAR. Your doctor may recommend you take birth control to prevent this.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think you may be pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if SANDOSTATIN LAR passes into breast milk. You should not breastfeed while undergoing treatment with SANDOSTATIN LAR.

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 can buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with SANDOSTATIN LAR and affect how it works.

These medicines can 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
- some radiotherapies such as those used for neuroendocrine tumours

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

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 LAR.

4. How do I receive SANDOSTATIN LAR?

Your doctor or other healthcare professional will administer your treatment directly into the muscles of your buttocks after they have combined the contents of the packet. It must ONLY be administered in this location and generally, the side you have it injected in will alternate each visit.

How much SANDOSTATIN LAR will I receive

Your doctor will decide how much SANDOSTATIN LAR you will receive based on your overall health, your condition and how you respond to therapy.

Generally

- The usual amount of SANDOSTATIN LAR you will receive is 20 mg, injected every 4 weeks.

- After about 3 months, the dose may be lowered to 10 mg or increased to 30 mg depending on how you respond to treatment. Your doctor will decide this.
- **If receiving SANDOSTATIN LAR for the treatment of neuroendocrine tumours**
- If you are receiving SANDOSTATIN LAR for the treatment of neuroendocrine tumours located in the gut, the usual dose is 30 mg every 4 weeks. Your doctor will decide how long you will receive SANDOSTATIN LAR.
- **If you are currently taking short-acting Sandostatin**
- Depending on your condition you may also need to continue injecting short-acting Sandostatin under the skin for about 2 weeks after your first injection of SANDOSTATIN LAR. Your doctor will tell you if this is the case.

When to receive SANDOSTATIN LAR

- Your doctor or other healthcare professional will discuss with you how often to get your injection.

If you forget to receive SANDOSTATIN LAR

If you miss your injection or cannot make your appointment for the injection, have it as soon as you can and then go back to your normal schedule. It will not do any harm if a dose is a few days late, but you could get some temporary re-appearance of symptoms until you get back on schedule.

Do not ask your doctor to give you a double dose to make up for the dose you missed.

If you receive too much SANDOSTATIN LAR

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

- Some of the symptoms that you have received too much may include hot flushes, fatigue, depression (sad mood), anxiety, lack of concentration and needing to urinate more frequently than usual.

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.

5. What should I know while I am receiving SANDOSTATIN LAR?

Things you should do

- Keep all your doctor's appointments so that your progress and overall health can be checked. These

include appointments to check on your liver, gall bladder, thyroid, pancreas, and blood sugar.

- Get your blood and urine tested promptly when asked by your doctor.
- Use contraception (birth control) to avoid becoming pregnant.

Call your doctor straight away if you:

- Become pregnant or think you may be pregnant. SANDOSTATIN LAR is not recommended in pregnancy because there is not much information about whether it is safe for you or your unborn baby.

Remind any doctor, dentist, or pharmacist you visit that you are receiving SANDOSTATIN LAR.

Things you should not do

- Do not take this medicine after the expiry date printed on the packaging, or if it is damaged, or shows signs of tampering.
- Do not take this medicine if it has been left out of the fridge for more than 24 hours.
- Do not give this medicine to someone else.

Driving or using machines

Be careful before you drive or use any machines or tools requiring your attention until you know how SANDOSTATIN LAR 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

This medicine may cause dizziness or lightheadedness in some people. Alcohol may make this worse.

Looking after your medicine

While you will generally receive SANDOSTATIN LAR at a hospital administered by doctor or other healthcare professional, you may be asked to store SANDOSTATIN LAR at home between visits.

Keep the vials in the carton until it is time to use them as this will protect them from light.

- If you are storing the vials for longer than one day, keep them in the carton, in the refrigerator between 2°C to 8°C. Do not freeze them.
- If you are scheduled to receive a SANDOSTATIN LAR injection that day, you can take it out of the fridge, but you must store it in a cool dry place (below 25°C) 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.

- **SANDOSTATIN LAR should only be administered by your Doctor or other healthcare professional**
- SANDOSTATIN LAR requires a healthcare professional to prepare your dose correctly.
- SANDOSTATIN LAR carton contents should reach room temperature (20°C to 25°C) before the contents are mixed to prepare for the injection. This will be a minimum of 30 minutes.
- The suspension (the mixture that occurs after the powder is combined with the liquid) must only be made up right before the injection.

Your doctor will have more detailed information about this if you have questions since you will not need to prepare or administer this yourself.

Keep it where young children cannot reach it.

When to discard your medicine

If any vials have been left out of the fridge for longer than one day (24 hours), do not use them.

The reconstituted suspension (mixture) contains no preservative. This medicine is for single use in one patient only. Your doctor or other healthcare professional will dispose of anything that is left over, after the injection, in a sharps container.

Getting rid of any unwanted medicine

After your doctor or other healthcare professional has administered your treatment, they will dispose of anything left over in a sharps container.

If your doctor has told you that you no longer need to receive this medicine or it is out of date or been left out of the fridge for too long, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
General wellness <ul style="list-style-type: none">• Feeling tired or weak• Headache• Temporary hair loss	Speak to your doctor if you have any of these less serious side effects and they worry you or are making you feel unwell.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Feeling a little short of breath <p>Gut problems</p> <ul style="list-style-type: none"> ● Abdominal pain/cramps ● Constipation or diarrhoea ● Bloating, wind, or change in bowel movements ● Indigestion, nausea, vomiting ● Loss of appetite <p>Skin problems</p> <ul style="list-style-type: none"> ● Pain, irritation, redness, rash or swelling at the injection site. ● Dry skin 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction</p> <ul style="list-style-type: none"> ● Red, itchy rash that is spreading. ● Itchy hives 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Swelling of the face, lips, tongue, or other parts of the body ● Trouble breathing, wheezing, shortness of breath <p>Signs of low blood sugar:</p> <ul style="list-style-type: none"> ● Excessive sweating, trembling, dizziness, hungry all the time. ● Feeling weak, irregular heartbeat (palpitations), feeling really tired. <p>Signs of high blood sugar:</p> <ul style="list-style-type: none"> ● Blurred vision ● Passing much less urine than normal or very dark urine <p>Thyroid problems:</p> <ul style="list-style-type: none"> ● Cold sweats, feeling hot and cold, feeling anxious ● Swelling of the neck ● Significant weight gain <p>Gall bladder/liver problems:</p>	<p>notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Severe pain, tenderness or swelling in the stomach or abdomen while feeling/being sick ● Yellowing of the skin and eyes, loss of appetite, generally feeling unwell ● Light coloured urine ● Gallstones, may present with back pain <p>Bleeding problems:</p> <ul style="list-style-type: none"> ● Increased bleeding or bruising (could be low level of platelets in blood). 	

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.

What SANDOSTATIN LAR contains

SANDOSTATIN LAR vials contain 10 mg, 20 mg or 30 mg of the active ingredient, octreotide (as acetate).

Active ingredient (main ingredient)	Octreotide
Other ingredients (inactive ingredients)	<u>Vial contents</u> <ul style="list-style-type: none">• mannitol• polyglactin glucose <u>Syringe contents</u> <ul style="list-style-type: none">• mannitol• carmellose sodium• poloxamer• water for injections
Potential allergens	-

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

What SANDOSTATIN LAR looks like

SANDOSTATIN LAR is a white to white with yellowish tint powder packed in a glass vial. The diluent (liquid) is a clear, colourless to slightly yellow or brown solution.

Each box of SANDOSTATIN LAR contains one 6mL glass vial of powder, a 3mL glass syringe already containing the diluent (liquid) to mix with the powder, a vial adaptor and safety injection needle.

The vial contents need to be suspended in diluent prior to injection. Your doctor will do this before they administer your treatment. If you have any questions about the contents of the pack, speak to your doctor.

SANDOSTATIN LAR is available as:

- SANDOSTATIN LAR octreotide (as acetate) 10 mg modified release injection plus diluent (AUST R 227962)
- SANDOSTATIN LAR octreotide (as acetate) 20 mg modified release injection plus diluent (AUST R 227963)
- SANDOSTATIN LAR octreotide (as acetate) 30 mg modified release injection plus diluent (AUST R 227964)

Who distributes SANDOSTATIN LAR

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