

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**SANDOSTATIN**[®]

Octreotide Injection

This Patient Medication Information is written for the person who will be taking **SANDOSTATIN**[®]. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **SANDOSTATIN**, talk to a healthcare professional.

What **SANDOSTATIN** is used for:

SANDOSTATIN is used in adults

- to control symptoms in patients with:
 - metastatic carcinoid tumours. **SANDOSTATIN** prevents severe diarrhoea and flushing caused by metastatic carcinoid tumours.
 - vasoactive intestinal peptide-secreting tumours (VIPomas). **SANDOSTATIN** treats excessive watery diarrhoea caused by these tumours.
 - acromegaly. Acromegaly is a condition where there is an overproduction of growth hormones by a gland in the brain.
- to prevent problems following pancreatic surgery
- for the emergency treatment of bleeding in the oesophagus and stomach in patients with liver disease. **SANDOSTATIN**, used with other interventions, provides better control of bleeding and early re-bleeding.

How **SANDOSTATIN** works:

SANDOSTATIN is believed to reduce symptoms by:

- reducing the overproduction of growth hormones made by the pituitary gland (a pea-sized gland located at the base of the brain). Too much growth hormone leads to an increase in the growth of tumours.
- slowing down the overproduction of some specific hormones and other related substances made by the stomach, bowels, or pancreas. This overproduction in hormones can cause flushing and diarrhoea.
- increasing water absorption in the body.

The ingredients in **SANDOSTATIN** are:

Medicinal ingredient: octreotide as octreotide acetate

Non-medicinal ingredients:

Ampoules: lactic acid, sodium hydrogen carbonate, mannitol and water for injection

SANDOSTATIN comes in the following dosage form(s):

Solution for injection (1 mL ampoules): 50 mcg/mL of octreotide as octreotide acetate.

Do not use SANDOSTATIN if:

- are allergic to octreotide acetate or to any other ingredients of SANDOSTATIN.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SANDOSTATIN. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure (*hypertension*)
- have problems with your blood sugar levels, either too high (*hyperglycaemia*) or too low (*hypoglycaemia*). Taking SANDOSTATIN can also result in diabetes. Your doctor will monitor your blood sugar levels at the beginning of your treatment or when your dosage is changed.
- have or had gallstones or other biliary problems. Long-term use of SANDOSTATIN may result in gallstones or other related problems.
- have or had pancreas problems
- have problems with your liver (e.g. liver cirrhosis)
- have problems with your kidneys and require dialysis
- have heart problems. Abnormal heart rate and rhythm have been reported during treatment with SANDOSTATIN. If you are taking any blood pressure medications, your doctor may adjust your dosage while on SANDOSTATIN.

Other warnings you should know about:

If you take SANDOSTATIN, you may experience the following:

- Growth of tumours. This can cause serious complications (i.e. vision problems). Your doctor will monitor your condition and may provide other treatments.
- Hypothyroidism (low thyroid hormone). If you receive long treatment with SANDOSTATIN your doctor may wish to check your thyroid function periodically.

Pregnancy and breastfeeding

If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your doctor.

- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SANDOSTATIN.
- Effective birth control methods should be used during treatment with SANDOSTATIN. Talk to your doctor about birth control methods that may be right for you.
- If you are taking SANDOSTATIN to treat acromegaly, there is an increase in risk of you developing the following conditions:
 - Diabetes during pregnancy
 - High blood pressure
 - Worsening of heart disease
- If you are breastfeeding or plan to breastfeed. It is not known if SANDOSTATIN passes into your breast milk. Do not breastfeed during your treatment with SANDOSTATIN.

Nutrition

- Taking SANDOSTATIN may alter your ability to absorb vitamin B12 and dietary fat. If you are receiving intravenous nutritional feeding, zinc levels in your body may also increase. Your doctor will monitor your levels of dietary fat, vitamin B12 and zinc during your treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SANDOSTATIN:

- drugs to control blood pressure (e.g. beta blockers, calcium channel blockers)
- drugs to control blood sugar (e.g. sulfonylureas, insulin, and diazoxide)
- cimetidine
- cyclosporine
- bromocriptine
- anti-diarrhoeal agents (affect fluid and electrolytes)
- lutetium (¹⁷⁷Lu) oxodotreotide (LUTATHERA®), a radiopharmaceutical drug. If you are going to get LUTATHERA treatment, your doctor may stop and/or change your treatment with SANDOSTATIN.

How to take SANDOSTATIN:

Usual dose:

- Your doctor will tell you how much SANDOSTATIN to take each day. The doctor will also tell you how to divide your dosage throughout the day.
- SANDOSTATIN is to be injected under your skin (subcutaneous injection).
- Pay close attention to the amount of drug you are taking into the syringe for injection. Make sure it is the amount your doctor has prescribed for you.

How to Prepare Your Injection of SANDOSTATIN:

You will receive your supply of SANDOSTATIN in ampoules. The ampoules should be visually inspected and not used in the presence of floating particles or discoloration.

Injecting the drug at room temperature, rather than cold from the refrigerator, may lessen the burning sensation that some patients may experience at the injection site.

Ampoules

1. Before breaking open the ampoule, tap the neck portion so that any medication that may be trapped will flow down into the bottom portion of the ampoule.
2. Once the ampoule is opened, insert the needle and pull back the plunger to fill the syringe with the desired amount of drug (your doctor or nurse will tell you how to read the markings on your syringe, so that you can fill it with the right amount of drug for your dose). Discard any unused medication.
3. Check to see if there are any air bubbles in the syringe. If bubbles do appear, hold the syringe upright (with the needle pointed up) and lightly tap the barrel. This should make the bubbles rise to the top of the syringe. Then gently press the plunger to push the bubbles out.

How to Inject Your Dose of SANDOSTATIN:

1. Choose the area of your hip, thigh, or abdomen where you want to make your injection.
2. Clean the site with a fresh alcohol wipe and keep it nearby.
3. Hold the syringe like a pencil, and remove the needle cap.
4. Use the thumb and forefinger of your other hand to gently pinch up a fold of skin at the place you want to inject. This will lift the subcutaneous tissue away from the muscle underneath.
5. Hold the syringe at a 45° angle and insert the entire length of the needle into the fold of skin in one quick motion.
6. Once the needle is inserted, let go of the skin.
7. Using your free hand, pull back on the plunger slightly to check whether you have placed the needle in a blood vessel (you don't want to). If any blood appears in the syringe, this is not a proper site for your injection. You will have to remove and discard the syringe and needle and start over.
8. Once the needle is inserted properly, slowly inject all of the medication.
9. When you are finished injecting the medicine, place your alcohol wipe where the needle enters the skin. Press lightly.
10. Withdraw the needle at the same angle it is inserted.
11. Gently hold the wipe on your skin for about five seconds.
12. Put the cap back on the needle and dispose of the syringe and needle safely. Do not reuse the syringe and needle. Single-use syringes and needles are used to reduce the chance of infection. Collect your used needles and syringes in a metal container, such as a coffee can, and then dispose of them in a covered garbage can. This will keep others (especially children) from injuring themselves.

Overdose:

If you think you, or a person you are caring for, have taken too much SANDOSTATIN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget to take a scheduled injection, check with your doctor. Do not double your dose at the next injection.

Possible side effects from using SANDOSTATIN:

These are not all the possible side effects you may have when taking SANDOSTATIN. If you experience any side effects not listed here, tell your healthcare professional.

- arm and leg feel heavy
- arthritis
- behaviour changes

- o anxiety, sadness, moody, bad temper
- congested nose
- constipation
- diarrhoea
- dizziness
- dry mouth
- fainting
- fatty stools, loose stools, discolouration of stools
- feeling of fullness in the stomach
- fever
- flatulence (wind)
- flu and cold-like symptoms
- flushing or hot flashes
- foot, back, joint and leg pain
- headache
- haemorrhoids
- hair loss
- leg cramps
- loss of appetite
- nausea
- nose bleeds
- ringing, buzzing, clicking or hissing in the ears
- sore throat
- stomach pain, stomach discomfort after meal
- swelling, pain, rash, burning sensation or bruising at injection site
- tiredness or inability to sleep
- unusual swelling of the arms, hands, legs, feet and ankles, face
- vomiting
- weakness or lack of energy
- weight gain

Treatment with SANDOSTATIN may cause a change in thyroid function tests and liver function tests.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Formation of gallstones in the gallbladder (<i>cholelithiasis</i>), inflammation of the gallbladder (<i>cholecystitis</i>) and inflammation of the bile duct (<i>cholangitis</i>): severe pain in the upper right abdomen which may last for several hours, particularly after a fatty meal, possible nausea or vomiting, fever		√	

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Vision problems		√	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		√	
Slow heartbeat (<i>bradycardia</i>)		√	
UNCOMMON			
Acute pancreatitis (inflammation of the pancreas gland causing severe stomach pain)			√
Diabetes, worsening diabetes, or high blood sugar: unusual thirst, frequent urination, fatigue, blurred vision		√	
Low blood sugar (<i>hypoglycaemia</i>): feeling hungry, dizziness, fast heartbeat, tingling, trembling, sweating, feeling tired		√	
Underactive thyroid gland (<i>hypothyroidism</i>) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck		√	
Liver inflammation (<i>hepatitis</i>); symptoms may include yellowing of the skin and eyes (jaundice), nausea, vomiting, loss of appetite, generally feeling unwell, itching, light-coloured urine		√	
Fast heartbeat (<i>tachycardia</i>)		√	
RARE			
Allergic skin reactions: rash, hives, itching, redness	√		
UNKNOWN			
Low level of platelet in blood (thrombocytopenia; increased bleeding or bruising, fatigue, weakness		√	
Allergic reaction (<i>anaphylaxis</i>) (difficulty in swallowing or breathing, rash, hives, swelling of			√

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
the face, lips, tongue or throat, tingling, possibly with a drop in blood pressure with dizziness or loss of consciousness)			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

SANDOSTATIN must be stored at 2 to 8 °C (in a refrigerator). However, you may leave your daily dose of SANDOSTATIN (ampoules) out at a room temperature of up to 30°C for up to 2 weeks. The ampoules should be opened just prior to administration and any unused portion **discarded**.

Keep the container in the outer carton in order to protect from light. Do not freeze.

Do not use SANDOSTATIN (ampoules) after the expiry date.

Keep out of reach and sight of children.

If you want more information about SANDOSTATIN:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca); or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrSANDOSTATIN® LAR®

Octreotide for Injectable Suspension

This Patient Medication Information is written for the person who will be taking SANDOSTATIN® LAR®. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about SANDOSTATIN LAR, talk to a healthcare professional.

What SANDOSTATIN LAR is used for:

SANDOSTATIN LAR is used in adults who are adequately being treated with octreotide injection for:

- metastatic carcinoid tumours. SANDOSTATIN LAR treats severe diarrhoea and flushing caused by metastatic carcinoid tumours
- vasoactive intestinal peptide-secreting tumours (VIPomas). SANDOSTATIN LAR treats excessive watery diarrhoea caused by these tumours.
- acromegaly. Acromegaly is a condition where there is an overproduction of growth hormones by a gland in the brain. SANDOSTATIN LAR is used to treat people with acromegaly:
 - o when other types of treatment for acromegaly (surgery or radiotherapy) are not suitable or haven't worked;
 - o to cover the interim period until the radiotherapy becomes fully effective.

How SANDOSTATIN LAR works:

SANDOSTATIN LAR is believed to provide treatment by:

- reducing the overproduction of growth hormones made by the pituitary gland (a pea-sized gland located at the base of the brain). Too much growth hormone leads to an increase in the growth of tumours.
- slowing down the overproduction of some specific hormones and other related substances made by the stomach, bowels, or pancreas. This overproduction in hormones can cause flushing and diarrhoea.
- increasing water absorption in the body.

The ingredients in SANDOSTATIN LAR are:

Medicinal ingredient: octreotide as octreotide acetate

Non-medicinal ingredients:

Powder (in vial): poly (DL-lactide-co-glycolide) and mannitol

Diluent (in prefilled syringe): carboxymethylcellulose sodium, mannitol, poloxamer 188 and sterile water

SANDOSTATIN LAR comes in the following dosage form(s):

SANDOSTATIN LAR is supplied in a kit, which includes:

- One glass vial
 - Powder for suspension (6 mL glass vial): 10 mg, 20 mg, or 30 mg of octreotide (as octreotide acetate);
- A pre-filled glass syringe containing 2 mL of diluent to be used for suspending the powder;
- One vial adapter to be used for delivering the diluent from the pre-filled syringe to the vial, without a needle;
- One 19G x 1.5" safety injection needle;
- An instruction booklet for detailed directions for use

Do not use SANDOSTATIN LAR if:

- are allergic to octreotide acetate or any other ingredients in SANDOSTATIN LAR and its package.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SANDOSTATIN LAR. Talk about any health conditions or problems you may have, including if you:

- have high blood pressure (*hypertension*)
- have problems with your blood sugar levels, either too high (*hyperglycaemia*) or too low (*hypoglycaemia*). Taking SANDOSTATIN LAR can also result in diabetes. Your doctor will monitor your blood sugar levels at the beginning of your treatment or when your dosage is changed.
- have or had gallstones or other biliary problems. Long-term use of SANDOSTATIN LAR may result in gallstones and other related problems.
- have or had pancreas problems
- have problems with your liver (e.g. *liver cirrhosis*)
- have problems with your kidneys and require dialysis
- have heart problems. Abnormal heart rate and rhythm have been reported during treatment with SANDOSTATIN LAR. If you are taking any blood pressure medications, your doctor may adjust your dosage while on SANDOSTATIN LAR.

Other warnings you should know about:

If you take SANDOSTATIN LAR, you may experience the following:

- Growth of tumours. This can cause serious complications (i.e. vision problems). Your doctor will monitor your condition and may provide other treatments.
- Hypothyroidism (low thyroid hormone). If you receive long-term treatment with SANDOSTATIN LAR your doctor may wish to check your thyroid function periodically.

Pregnancy and breastfeeding

If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your doctor.

- Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SANDOSTATIN LAR
- Effective birth control methods should be used during treatment with SANDOSTATIN LAR. Talk to your doctor about birth control methods that may be right for you.
- If you are taking SANDOSTATIN LAR to treat acromegaly, there is an increase in risk of you developing the following conditions:
 - Diabetes during pregnancy

- High blood pressure
- Worsening of heart disease
- If you are breastfeeding or plan to breastfeed. It is not known if SANDOSTATIN LAR passes into your breast milk. Do not breastfeed during your treatment with SANDOSTATIN LAR.

Nutrition

Taking SANDOSTATIN LAR may alter your ability to absorb vitamin B12 and dietary fat. If you are receiving an intravenous nutritional feeding, zinc levels in your body may also increase. Your doctor will monitor your levels of dietary fat, vitamin B12 and zinc during your treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SANDOSTATIN LAR

- drugs to control blood pressure (e.g. beta blockers, calcium channel blockers)
- drugs to control blood sugar (e.g. sulfonylureas, insulin, and diazoxide)
- cimetidine
- cyclosporine
- bromocriptine
- anti-diarrheal agents (affect fluid and electrolytes)
- lutetium ($^{177\text{Lu}}$) oxodotreotide (LUTATHERA[®]), a radiopharmaceutical drug. If you are going to get LUTATHERA treatment, your doctor may stop and/or change your treatment with SANDOSTATIN LAR.

How to take SANDOSTATIN LAR:

- Your doctor or nurse will give you your injection of SANDOSTATIN LAR.
- SANDOSTATIN LAR is injected into the muscles of your buttocks. For each injection, the doctor or nurse should alternate between the left and right buttocks.
- The vials should be examined before use. Do not use if the vial is damaged, the powder is discoloured or contains unusual particulate matter.

Usual dose:

Dose: One vial every 4 weeks

Usual starting dose: 20 mg every 4 weeks. The dose may be changed later depending on your condition.

Overdose:

If you think you, or a person you are caring for, have taken too much SANDOSTATIN LAR, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss your injection, please contact your doctor as soon as possible.

Possible side effects from using SANDOSTATIN LAR:

These are not all the possible side effects you may have when taking SANDOSTATIN LAR. If you experience any side effects not listed here, tell your healthcare professional.

- behaviour changes
 - anxiety, sadness, moody, nervous, inability to sleep
- breast pain
- cold
 - runny or stuffy nose, sore throat, cough, sinus congestion, body aches, sneezing
- constipation
- cramps
- diarrhoea
- discoloration of stools
- dizziness
- fainting
- fatty stools
- feeling of fullness in the stomach
- fever
- flatulence (wind)
- flu-like symptoms
- hair loss
- having the urge to empty your bowels
- headache
- hot flashes
- increased sweating
- indigestion
- joint, leg(s), muscle, or back pain
- loss of appetite
- nausea
- nose bleeds
- pain, swelling and/or rash at injection site
- rash or itchy skin
- stomach discomfort after meal
- stomach pain
- tiredness
- unusual swelling of the arms, hands, legs, feet and ankles, face
- vomiting
- weakness or lack of energy

Treatment with SANDOSTATIN LAR may cause a change in thyroid function tests and liver function tests.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Formation of gallstones in the gallbladder (<i>cholelithiasis</i>), inflammation of the gallbladder (<i>cholecystitis</i>) and inflammation of the bile ducts (<i>cholangitis</i>) (severe pain in the upper right abdomen which may last for several hours, particularly after a fatty meal, possible nausea or vomiting, fever)		√	
Anaemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		√	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		√	
Slow heartbeat (<i>bradycardia</i>)		√	
UNCOMMON			
Acute pancreatitis (inflammation of the pancreas gland causing severe stomach pain)			√
Low blood sugar (<i>hypoglycaemia</i>): feeling hungry, dizziness, fast heartbeat, tingling, trembling, nervousness, sweating, feeling tired		√	
Diabetes, worsening of diabetes, or high blood sugar: unusual thirst, frequent urination, fatigue, blurred vision		√	
Underactive thyroid gland (<i>hypothyroidism</i>) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck		√	
Liver inflammation (<i>hepatitis</i>); symptoms may include yellowing		√	

Frequency/Side Effect/Symptom	Talk to your health professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
of the skin and eyes (jaundice), nausea, vomiting, loss of appetite, generally feeling unwell, itching, light-coloured urine			
Fast heartbeat (<i>tachycardia</i>)		√	
RARE			
Allergic skin reactions: rash, hives, itching, redness	√		
UNKNOWN			
Low level of platelet in blood (<i>thrombocytopenia</i>); increased bleeding or bruising, fatigue, weakness		√	
Allergic reaction (<i>anaphylaxis</i>) (difficulty in swallowing or breathing, rash, hives, swelling of the face, lips, tongue or throat, tingling, possibly with a drop in blood pressure with dizziness or loss of consciousness)			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The SANDOSTATIN LAR powder and diluent should be stored at 2 to 8 °C (in a refrigerator). Do not freeze. Keep the vial in the outer carton in order to protect it from light. The vials should be allowed to reach room temperature on the day of the injection but must be protected from light. However, the suspension must only be prepared immediately before injection. Once removed from the refrigerator, the vials will usually reach room temperature within 30 to 60 minutes.

Do not use SANDOSTATIN LAR after the expiry date.

Keep out of reach and sight of children.

If you want more information about SANDOSTATIN LAR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca); or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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