

PART III: CONSUMER INFORMATION

SANDOSTATIN® (octreotide acetate injection)

This leaflet is part III of a three-part "Product Monograph" published when SANDOSTATIN® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SANDOSTATIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is SANDOSTATIN used for?

SANDOSTATIN (octreotide acetate) is used:

- to control symptoms in patients with gastroenteropancreatic (GEP) endocrine tumors or with acromegaly.
- for the prevention of complications following pancreatic surgery.
- for the emergency treatment of bleeding varices (stretched veins) in the esophagus and stomach in patients with liver disease and as protection from rebleeding.

What is a Gastroenteropancreatic (GEP) Endocrine Tumor?

GEP endocrine tumors are growths that have developed from endocrine cells in the gastrointestinal tract (the stomach, intestines, appendix) or the pancreas.

Some symptoms come about because GEP endocrine tumors produce and secrete chemical substances called peptides, i.e. small proteins in excess – overloading the system.

The over-secretion of peptides cause diarrhea and flushing.

Carcinoid tumors (generally occurring in the esophagus, stomach, intestines, appendix, and lungs) and VIPomas (almost always occurring in the pancreas) are the most common type of GEP endocrine tumor.

Diarrhea can cause dehydration, it is therefore very important to control it and replace the loss of water and electrolytes as quickly as possible.

What is Acromegaly?

Acromegaly is a life-time, uncommon, debilitating disease characterized by changes in facial bone structure and specific hormonal abnormalities.

Acromegaly is the result of an overproduction of growth hormone by the pituitary gland (a pea-sized gland located at the base of the brain). Uncontrolled disease may lead to arthritis, cardiac and neurologic problems. Approximately 20% to 30% of acromegalic patients also demonstrate high blood pressure.

What SANDOSTATIN (octreotide acetate) does?

GEP Endocrine Tumors:

SANDOSTATIN works to help slow down the release of the peptides that cause diarrhea and flushing. It also stimulates water absorption.

Acromegaly:

SANDOSTATIN has been shown to lower the overproduction of growth hormone by the pituitary gland.

When it should not be used:

SANDOSTATIN should not be used if you are allergic to the active ingredient octreotide or to any other ingredient of the formulation.

What the medicinal ingredient is:

octreotide acetate.

What the important nonmedicinal ingredients are:

The ampoules contain: lactic acid, sodium hydrogen carbonate and water for injection.

The multidose vials contain: lactic acid, sodium hydrogen carbonate, mannitol and water for injection.

What dosage forms it comes in:

SANDOSTATIN (octreotide acetate) is a solution supplied in:

- 1 mL ampoules, each containing 50 µg, 100 µg or 500 µg of octreotide as acetate. SANDOSTATIN is available in boxes of 5 ampoules.

and

- 5 mL multidose vials. Each vial contains 1000 µg of octreotide as acetate (200 µg/mL).

WARNINGS AND PRECAUTIONS

BEFORE you use SANDOSTATIN talk to your doctor or pharmacist if you:

- have high blood pressure (hypertension),
- have problems with your blood sugar levels, either too high or too low (hypoglycaemia),

- have gallstones or have had gallstones in the past, as prolonged use of SANDOSTATIN may result in gallstone formation,
- have problems with your liver (e.g. liver cirrhosis),
- have problems with your kidneys and require dialysis,
- are pregnant, suspect that you may be pregnant,
- are breast feeding,
- have heart problems.

If you receive long treatment with SANDOSTATIN your doctor may wish to check your thyroid function periodically.

There is very little experience with the use of SANDOSTATIN in children.

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SANDOSTATIN include:

- 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)

Please inform your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

SANDOSTATIN is best injected between meals or on retiring to bed. This may reduce the gastrointestinal side effects of SANDOSTATIN.

PROPER USE OF THIS MEDICATION

Usual dose:

Your doctor will tell you how much SANDOSTATIN to take each day. SANDOSTATIN is to be injected under your skin (subcutaneous injection). The doctor will also tell you how to divide your dosage through the day.

How to Prepare Your Injection of SANDOSTATIN?

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

a) 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.

b) Multidose Vials

1. Peel off the aluminum seal.
2. Wipe the top of the vial with an alcohol swab.
3. Remove the cap from the needle and insert the needle into the vial through the rubber stopper.
4. Leave the needle in the bottle.
5. Turn the vial and the syringe upside down. Keep the needle tip within the liquid. Pull the plunger and carefully withdraw the prescribed amount of SANDOSTATIN (your doctor or nurse will tell you how to read the markings on the syringe so that you fill it with the correct amount of drug for your dose).
6. Turn the bottle and syringe back upright.
7. Withdraw the needle from the vial.
8. 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.

Important Points to Remember

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.

Missed Dose:

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

Overdose:

No life-threatening reactions have been reported after overdosage of SANDOSTATIN.

If you think you have injected more SANDOSTATIN than you should, contact your doctor or poison control center in your area.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines SANDOSTATIN may cause some side effects. If you experience any of these, tell your doctor.

Some patients have experienced a burning sensation at the injection site. For most people, the burning lasts only a few moments. Injecting the drug at room temperature rather than cold from the refrigerator may alleviate the burning sensation.

Serious side effects

- Gallstones, leading to sudden back pain.
- Too much or too little sugar in the blood.
- 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).
- Impaired glucose tolerance.
- Irregular heart beat (slow or fast).
- Thirst, low urine output, dark urine, dry flushed skin.
- Hypersensitivity (allergic) reactions including skin rash.
- A type of an allergic reaction (anaphylaxis) which causes 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.
- Acute inflammation of the pancreas gland causing severe stomach pain (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.
- Low level of platelet in blood (thrombocytopenia); increased bleeding or bruising, fatigue, weakness.

Other side effects

The side effects listed below are usually mild and tend to disappear as treatment progresses.

- nausea
- vomiting
- stomach pain
- diarrhea
- feeling of fullness in the stomach
- flatulence (wind)
- loss of appetite
- constipation
- headache
- stomach discomfort after meal
- fatty stools
- loose stools
- discoloration of faeces
- dizziness
- change in liver function tests
- hair loss
- shortness of breath.

Since gallstones may occasionally form during prolonged use of SANDOSTATIN, your doctor may wish to check your gallbladder periodically.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Your medication should be withheld or stopped. Talk with your doctor.
		Only if severe	In all cases	
Common	- Formation of gallstones in the gallbladder (severe pain in the upper right abdomen which may last for several hours, particularly after a fatty meal, possible nausea or vomiting)		√	
Uncommon	- Acute pancreatitis (inflammation of the pancreas gland causing severe stomach pain)			√
)			√
	- Diabetes (symptoms include unusual thirst, frequent urination, extreme fatigue or lack of energy, tingling or numbness in the hands or feet)		√	
	- Underactive thyroid gland (hypothyroidism) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Your medication should be withheld or stopped. Talk with your doctor.
		Only if severe	In all cases	
	- 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 heart beat (slow or fast)		√	
Unknown	- Low level of platelet in blood (thrombocytopenia; increased bleeding or bruising, fatigue, weakness)		√	
	- Allergic reaction (anaphylaxis) (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)			√

This is not a complete list of side effects. For any unexpected effects while taking SANDOSTATIN, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

SANDOSTATIN is a registered trademark

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HOW TO STORE IT

SANDOSTATIN must be stored at 2° to 8°C (in a refrigerator). However, you may leave your daily dose of SANDOSTATIN (ampoules or multidose vials) 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 or multidose vials) after the expiry date.

Keep in a safe place out of reach and sight of children and pets.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca

PART III: CONSUMER INFORMATION

SANDOSTATIN® LAR® (octreotide acetate for injectable suspension)

This leaflet is part III of a three-part "Product Monograph" published when SANDOSTATIN® LAR® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SANDOSTATIN LAR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What is SANDOSTATIN LAR used for?

SANDOSTATIN LAR (octreotide acetate) is used to control symptoms associated with gastroenteropancreatic (GEP) endocrine tumors and acromegaly in patients who are adequately controlled with SANDOSTATIN®.

What is a Gastroenteropancreatic (GEP) Endocrine Tumor?

GEP endocrine tumors are growths that have developed from endocrine cells in the gastrointestinal tract (the stomach, intestines, appendix) or the pancreas.

Some symptoms come about because GEP endocrine tumors produce and secrete chemical substances called peptides, i.e. small proteins in excess – overloading the system.

- The over-secretion of peptides cause diarrhea and flushing.

Carcinoid tumors (generally occurring in the esophagus, stomach, intestines, appendix, and lungs) and VIPomas (almost always occurring in the pancreas) are the most common type of GEP endocrine tumor.

Diarrhea can cause dehydration, it is therefore very important to control it and replace the loss of water and electrolytes as quickly as possible.

What is Acromegaly?

Acromegaly is a life-time, uncommon, debilitating disease characterized by changes in facial bone structure and specific hormonal abnormalities.

Acromegaly is the result of an overproduction of growth hormone by the pituitary gland (a pea-sized gland located at the base of the brain). Uncontrolled disease may lead to arthritis, cardiac and neurologic problems. Approximately 20% to 30% of acromegalic patients also demonstrate high blood pressure.

What SANDOSTATIN (octreotide acetate) does?

GEP Endocrine Tumors:

SANDOSTATIN works to help slow down the release of the peptides that cause diarrhea and flushing. It also stimulates water absorption.

Acromegaly:

SANDOSTATIN LAR has been shown to lower the overproduction of growth hormone by the pituitary gland

When it should not be used:

SANDOSTATIN LAR should not be given to anyone who is allergic to octreotide or any other ingredient of the formulation.

What the medicinal ingredient is:

octreotide acetate.

What the important nonmedicinal ingredients are:

The powder contains: poly (DL-lactide-co-glycolide) and mannitol.

The diluent contains: carboxymethylcellulose sodium, mannitol, poloxamer 188 and sterile water.

What dosage forms it comes in:

SANDOSTATIN LAR is available as powder in vials and is supplied in a kit which includes:

- One glass vial of SANDOSTATIN LAR containing either 10, 20 or 30 mg of octreotide (as acetate) slow release;
- 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;
- A package insert for dosage and administration and detailed directions for use.

WARNINGS AND PRECAUTIONS

BEFORE you use SANDOSTATIN LAR talk to your doctor or pharmacist if you:

- have high blood pressure (hypertension),
- have problems with your blood sugar levels, either too high or too low (hypoglycaemia),

- have gallstones or have had gallstones in the past, as prolonged use of SANDOSTATIN LAR may result in gallstone formation,
- have problems with your liver (e.g. liver cirrhosis),
- have problems with your kidneys and require dialysis,
- are pregnant or suspect that you may be pregnant,
- are breast feeding.
- have heart problems.

If you receive long treatment with SANDOSTATIN LAR your doctor may wish to check your thyroid function periodically.

There is very little experience with the use of SANDOSTATIN in children.

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with SANDOSTATIN LAR include:

- 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)

Please inform your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

PROPER USE OF THIS MEDICATION

SANDOSTATIN LAR is to be given to you by your doctor or nurse as an injection into the muscle of the buttocks. With repeated administration the left and right buttock should be used alternately.

Inspect the vials. Do not use if the vial is damaged, the powder is discoloured, or contains unusual particulate matter.

Dose: One vial every 4 weeks

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

Missed Dose:

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

as possible.

Overdose:

No life-threatening reactions have been reported after overdose of SANDOSTATIN LAR.

If you think you have been given more SANDOSTATIN LAR than you should, talk to your doctor or nurse immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines SANDOSTATIN LAR may cause some side effects. If you experience any of these, tell your doctor.

A few people experience pain at the injection site, which usually lasts for only a short time (usually about one hour), and sometimes swelling and rash.

Some side effects can be serious

- Gallstones, leading to sudden back pain.
- Too much or too little sugar in the blood.
- 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).
- Impaired glucose tolerance.
- Irregular heart beat (slow or fast).
- Thirst, low urine output, dark urine, dry flushed skin.
- Hypersensitivity (allergic) reactions including skin rash.
- A type of an allergic reaction (anaphylaxis) which causes 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.
- Acute inflammation of the pancreas gland causing severe stomach pain (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.
- Low level of platelet in blood (thrombocytopenia); increased bleeding or bruising, fatigue, weakness.

Other side effects

The side effects listed below are usually mild and tend to disappear as treatment progresses.

- nausea
- vomiting

- stomach pain
- diarrhea
- feeling of fullness in the stomach
- flatulence (wind)
- loss of appetite
- constipation
- headache
- stomach discomfort after meal
- fatty stools
- discoloration of faeces
- dizziness
- change in liver function tests
- hair loss
- shortness of breath.

Since gallstones may occasionally form during prolonged use of SANDOSTATIN, your doctor may wish to check your gallbladder periodically.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Your medication should be withheld or stopped. Talk with your doctor.
		Only if severe	In all cases	
Common	- Formation of gallstones in the gallbladder (severe pain in the upper right abdomen which may last for several hours, particularly after a fatty meal, possible nausea or vomiting)		√	
Uncommon	- Acute pancreatitis (inflammation of the pancreas gland causing severe stomach pain)			√
)			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Your medication should be withheld or stopped. Talk with your doctor.
		Only if severe	In all cases	
	- Diabetes (symptoms include unusual thirst, frequent urination, extreme fatigue or lack of energy, tingling or numbness in the hands or feet)		√	
	- Underactive thyroid gland (hypothyroidism) causing changes in heart rate, appetite or weight; tiredness, feeling cold, or swelling at the front of the neck.		√	
	- 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 heart beat (slow or fast)		√	
Unknown	- Low level of platelet in blood (thrombocytopenia; increased bleeding or bruising, fatigue, weakness)		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Your medication should be withheld or stopped. Talk with your doctor.
	Only if severe	In all cases	
- Allergic reaction (anaphylaxis) (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)			√

This is not a complete list of side effects. For any unexpected effects while taking SANDOSTATIN LAR, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

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 in a safe place out of reach and sight of children and pets.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals

Canada Inc., at:
1-800-363-8883

This leaflet was prepared by
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