

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SANDOSTATIN**[®]

Octreotide Acetate Injection

Read this carefully before you start taking **SANDOSTATIN**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your health professional about your medical condition and treatment and ask if there is any new information about **SANDOSTATIN**.

What is SANDOSTATIN 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 does SANDOSTATIN work?

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.

What are the ingredients in SANDOSTATIN?

Medicinal ingredient: octreotide as octreotide acetate

Non-medicinal ingredients

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

Multidose vials: lactic acid, sodium hydrogen carbonate, mannitol, phenol and water for injection

SANDOSTATIN comes in the following dosage forms:

- Solution for injection (1 mL ampoules): 50 mcg/mL or 100 mcg/mL of octreotide as acetate.

- Solution for injection (5 mL multidose vials): 200 mcg/mL of octreotide as acetate.

Do not use SANDOSTATIN if you:

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

To help avoid side effects and ensure proper use, talk to your health 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 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 health 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 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.

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.

Multidose Vials

1. Peel off the aluminium 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.

Overdose:

If you think you, or a person you are caring for, have injected too much SANDOSTATIN, contact a health professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are 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 health professional.

- arm and leg feel heavy
- arthritis
- behaviour changes
 - 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			
Symptom / effect	Talk to your health professional		Stop taking 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		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your health professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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			
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			

Serious side effects and what to do about them			
Symptom / effect	Talk to your health professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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 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 health 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 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 out of reach and sight of children.

If you want more information about SANDOSTATIN:

- Talk to your health professional

- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Health Canada 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.

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LUTATHERA is a trademark

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SANDOSTATIN® LAR®**

Octreotide acetate injection

Read this carefully before you start taking **SANDOSTATIN® LAR®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your health professional about your medical condition and treatment and ask if there is any new information about **SANDOSTATIN LAR**.

What is SANDOSTATIN LAR used for?

SANDOSTATIN LAR is used in adults who are adequately being treated with SANDOSTATIN 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:
 - when other types of treatment for acromegaly (surgery or radiotherapy) are not suitable or haven't worked;
 - to cover the interim period until the radiotherapy becomes fully effective.

How does SANDOSTATIN LAR work?

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.

What are the ingredients in SANDOSTATIN LAR?

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 forms:

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 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 you:

- 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 health 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 health 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 have been given too much SANDOSTATIN LAR, contact your health professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are 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 health 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			
Symptom / effect	Talk to your health professional		Stop taking 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,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your health professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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 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		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your health professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
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 health 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health 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 health professional
- Find the full product monograph that is prepared for health professionals and includes this Patient Medication Information by visiting the Health Canada 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.

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