

PART III: CONSUMER INFORMATION

Pr Sandoz Candesartan Plus

(candesartan cilexetil/hydrochlorothiazide tablets)

Read this carefully before you start taking Sandoz Candesartan Plus and each time you get a refill. This leaflet is a summary and will not tell you everything about Sandoz Candesartan Plus. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about Sandoz Candesartan Plus.

ABOUT THIS MEDICATION

What the medication is used for:

Sandoz Candesartan Plus lowers high blood pressure.

What it does:

Sandoz Candesartan Plus contains a combination of 2 drugs, candesartan cilexetil and hydrochlorothiazide:

- Candesartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking Sandoz Candesartan Plus regularly even if you feel fine.

When it should not be used:

Do not take Sandoz Candesartan Plus if you:

- Are allergic to candesartan cilexetil, hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Have severe liver disease.
- Have severe kidney disease.
- Are allergic to any sulphonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”.
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez®) and you have diabetes or kidney disease.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat or sudden difficulty breathing or swallowing to any ARB (any drug in the same class as candesartan cilexetil). Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have difficulty urinating or produce no urine.

- Are pregnant or intend to become pregnant. Taking Sandoz Candesartan Plus during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. Sandoz Candesartan Plus passes into breast milk.
- Are less than 1 year old.
- Have gout.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption because lactose monohydrate is a non-medicinal ingredient in Sandoz Candesartan Plus.

What are the medicinal ingredients:

Candesartan cilexetil and hydrochlorothiazide.

What the nonmedicinal ingredients are:

Sandoz Candesartan Plus tablets contain the following nonmedicinal ingredients: carrageenan, corn starch, croscarmellose sodium, ferric oxide black (for 32 mg/12.5 mg and 32 mg/25 mg only), ferric oxide red, ferric oxide yellow (for 16 mg/12.5 mg and 32 mg/12.5 mg only), lactose monohydrate, magnesium stearate, povidone and titanium dioxide (for 32 mg/25 mg only).

What dosage forms it comes in:

Tablets in three strengths:

16 mg / 12.5 mg, is available in blister packs of 30 tablets and in bottles of 100 or 500 tablets.

32 mg / 12.5 mg is available in blister packs of 30 tablets and in bottles of 30, 100 or 500 tablets.

32 mg / 25 mg is available in blister packs of 30 tablets and in bottles of 30, 100 or 500 tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

Sandoz Candesartan Plus should not be used during pregnancy. If you discover that you are pregnant while taking Sandoz Candesartan Plus, stop the medication and contact your doctor, nurse or pharmacist as soon as possible.

Before you use Sandoz Candesartan Plus talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
- Have a liver disorder.
- Have a kidney disorder.

- Are taking a medicine that contains aliskiren, such as Rasilez[®], used to lower high blood pressure. The combination with Sandoz Candesartan Plus is not recommended.
- Are taking an angiotensin converting enzyme inhibitor (ACEI). You can recognize ACEIs because their medicinal ingredient ends in ‘-PRIL’.
- Have narrowing of an artery or a heart valve.
- Have heart failure.
- Have diabetes, liver, heart or kidney disease.
- Have lupus.
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”) or other drugs that may increase potassium levels (e.g., heparin, co-trimoxazole).
- Are on a low-salt diet.
- Are less than 18 years old.
- Are having any kind of surgery or dental procedure with anesthesia.
- Have had a heart attack or stroke.
- Have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Risk of skin cancer:

Sandoz Candesartan Plus contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking Sandoz Candesartan Plus for many years (more than 3) or at a high dose.

While taking Sandoz Candesartan Plus:

- Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
- Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in Sandoz Candesartan Plus can cause Sudden Eye Disorders:

- **Myopia:** sudden nearsightedness or blurred vision.
- **Glaucoma:** an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting Sandoz Candesartan Plus.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you

respond to Sandoz Candesartan Plus. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor or nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Sandoz Candesartan Plus:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome.
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amantadine.
- Amphotericin B, an antifungal drug
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Other blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez[®]), or angiotensin converting enzyme inhibitors (ACEIs). When taken in combination with Sandoz Candesartan Plus, they may cause excessively low blood pressure.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Cyclosporine.
- Digoxin, a heart medication.
- Drugs that slow down or speed up bowel function, including atropine, biperiden, domperidone and metoclopramide.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen and celecoxib.
- Pressor amines such as norepinephrine.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine.

PROPER USE OF THIS MEDICATION

Take Sandoz Candesartan Plus exactly as prescribed. It is recommended to take your dose at about the same time everyday.

Sandoz Candesartan Plus can be taken with or without food but it should be taken the same way each day. Swallow Sandoz Candesartan Plus with a glass of water.

If Sandoz Candesartan Plus causes upset stomach, take it with food or milk.

Do not transfer Sandoz Candesartan Plus to other pill containers. To protect your Sandoz Candesartan Plus tablets, keep them in the original package.

Remember to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

Usual Adult Dose:

Usual maintenance dose is 1 tablet daily

The dosage of Sandoz Candesartan Plus is individualized.

Sandoz Candesartan Plus is not for initial therapy. You must first be stabilized on the individual components (candesartan cilexetil and hydrochlorothiazide) of Sandoz Candesartan Plus.

Overdose:

If you think you have taken too much Sandoz Candesartan Plus, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of Sandoz Candesartan Plus and remember within 12 hours, you should take your usual dose as soon as possible. Then go back to your regular schedule. But if it is more than 12 hours when you remember, do not take the missed dose. Just take the next dose on time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- back or leg pain, muscle cramps, spasms and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- bleeding under skin, rash, red patches on the skin, itching
- drowsiness, insomnia
- reduced libido
- throat infections
- cough

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Sandoz Candesartan Plus can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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

Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Com-mon	Low Blood Pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up	√		
	Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		√	
	Tachycardia: increased heart beats		√	
	Edema: swelling of hands, ankles or feet		√	
	Non-melanoma skin cancer: lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		√	
Uncom-mon	Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
Increased blood sugar: frequent, urination, thirst, and hunger	√		
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Rare	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine	√	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms	√	
	Decreased Platelets: bruising, bleeding, fatigue and weakness	√	

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

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very Rare	Toxic Epidermal Necrolysis: severe skin peeling, especially in the mouth and eyes		√
Not known	Eye disorders: -Myopia: sudden near sightedness or blurred vision -Glaucoma: increased pressure in your eyes, eye pain		√
	Anemia: fatigue, loss of energy, weakness, shortness of breath	√	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting	√	
	Lupus: Conditions may be activated or made worse	√	

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

HOW TO STORE IT

- Although Sandoz Candesartan Plus tablets are protected in their package, it is best to store them at normal room temperature between 15 and 30°C and in a dry place. Do not keep Sandoz Candesartan Plus in the bathroom.
- **Keep Sandoz Candesartan Plus out of sight and reach of children.** Never take medicine in front of small children as they will want to copy you.

- Do not keep or use Sandoz Candesartan Plus after the expiry date indicated on the package. Unused medicines, which you know you will no longer need, should be carefully discarded. You may wish to seek advice from your pharmacist.

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/adverse-reaction-reporting.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.

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be found at www.sandoz.com,

or by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062

Or by written request at:
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or by e-mail at:
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