

PART III: CONSUMER INFORMATION

Pr CANDESARTAN HCT

(candesartan cilexetil/hydrochlorothiazide tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:

CANDESARTAN HCT lowers high blood pressure.

What it does:

CANDESARTAN HCT 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 CANDESARTAN HCT regularly even if you feel fine.

When it should not be used:

Do not take CANDESARTAN HCT 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 CANDESARTAN HCT during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. CANDESARTAN HCT 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 CANDESARTAN HCT.

What are the medicinal ingredients:

Candesartan cilexetil and hydrochlorothiazide.

What the nonmedicinal ingredients are:

CANDESARTAN HCT tablets contain the following nonmedicinal ingredients: carrageenan, corn starch, croscarmellose sodium, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate, povidone.

What dosage forms it comes in:

Tablets in one strength:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

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

Before you use CANDESARTAN HCT 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 CANDESARTAN HCT 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.

Hydrochlorothiazide in CANDESARTAN HCT 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 CANDESARTAN HCT.

You may become sensitive to the sun while taking CANDESARTAN HCT. Exposure to sunlight should be minimized until you know how you respond.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to CANDESARTAN HCT. 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 CANDESARTAN HCT:

- 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 CANDESARTAN HCT, 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 CANDESARTAN HCT exactly as prescribed. It is recommended to take your dose at about the same time everyday.

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

If CANDESARTAN HCT causes upset stomach, take it with food or milk.

Do not transfer CANDESARTAN HCT to other pill containers. To protect your CANDESARTAN HCT 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 CANDESARTAN HCT is individualized.

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

Overdose:

If you think you have taken too much CANDESARTAN HCT, 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 CANDESARTAN HCT 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.

CANDESARTAN HCT 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 with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	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		√	

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Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Tachycardia: increased heart beats		√	
	Edema: swelling of hands, ankles or feet		√	
Uncommon	Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	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		√	

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Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		√	
Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
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 CANDESARTAN HCT, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

- Although CANDESARTAN HCT 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 CANDESARTAN HCT in the bathroom.
- **Keep CANDESARTAN HCT 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 CANDESARTAN HCT 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 SUSPECTED SIDE EFFECTS

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 0701E
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.

MORE INFORMATION

This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sivem Pharmaceuticals ULC, at 1-855-788-3153

Or at: www.sivem.ca

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