

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **CANDESARTAN HCT**

Candesartan cilexetil and 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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CANDESARTAN HCT**.

Serious Warnings and Precautions

- **CANDESARTAN HCT** should not be used during pregnancy. Taking **CANDESARTAN HCT** during pregnancy can cause injury or even death to your baby. If you discover that you are pregnant while taking **CANDESARTAN HCT**, stop the medication and contact your healthcare professional as soon as possible.

What is CANDESARTAN HCT used for?

CANDESARTAN HCT is used in adults to lower high blood pressure.

How does CANDESARTAN HCT work?

CANDESARTAN HCT is a combination of 2 drugs, candesartan cilexetil and hydrochlorothiazide:

- Candesartan is an angiotensin receptor blocker (ARB). It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This also helps to lower 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.

What are the ingredients in CANDESARTAN HCT?

Medicinal ingredients: candesartan cilexetil and hydrochlorothiazide.

Non-medicinal ingredients: carrageenan, corn starch, croscarmellose sodium, ferric oxide red, ferric oxide yellow, lactose monohydrate, magnesium stearate and povidone.

CANDESARTAN HCT comes in the following dosage forms:

Tablets: 16 mg / 12.5 mg of candesartan cilexetil / hydrochlorothiazide.

Do not use CANDESARTAN HCT if:

- You are allergic to candesartan cilexetil, hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- You have severe liver disease.
- You have severe kidney disease.
- You are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”.

- You have diabetes or kidney disease and are already taking a blood pressure-lowering medicine that contains aliskiren.
- You 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 healthcare professional that this has happened to you.
- You have difficulty urinating or produce no urine.
- You are pregnant or intend to become pregnant. Taking CANDESARTAN HCT during pregnancy can cause injury and even death to your baby.
- You are breastfeeding. CANDESARTAN HCT passes into breast milk.
- You have gout.
- You have one of the following rare hereditary diseases, because CANDESARTAN HCT contains lactose:
 - Galactose intolerance,
 - Lapp lactase deficiency,
 - Glucose-galactose malabsorption.

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

- Are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
- Have a liver or kidney disorder.
- 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, a potassium- sparing diuretic (a specific kind of "water pill") or other drugs that may increase potassium levels such as heparin, co-trimoxazole.
- Are on a low-salt diet.
- Have had a heart attack or stroke.
- Have had breathing or lung problems (including inflammation or fluid in the lungs) after taking hydrochlorothiazide in the past. If you develop any severe shortness of breath or difficulty breathing after taking CANDESARTAN HCT, stop the medication and seek medical attention immediately.
- 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.

Other warnings you should know about:

Use of anesthesia: If you are about to have a surgery or dental procedure with anesthesia, be sure to tell your healthcare professional that you are taking CANDESARTAN HCT.

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

While taking CANDESARTAN HCT:

- 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 healthcare professional 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.

Sudden eye disorders: Treatment with hydrochlorothiazide in CANDESARTAN HCT can cause sudden eye problems such as:

- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes.

These eye disorders are related and can develop within hours to weeks of starting CANDESARTAN HCT. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this. If you experience the above symptoms, stop taking CANDESARTAN HCT and seek immediate medical help.

Monitoring: During your treatment with CANDESARTAN HCT, your healthcare professional may monitor:

- Your kidney function.
- Your blood pressure.
- The amount of electrolytes in your blood (such as potassium).

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 occur, especially after the first dose and when the dose is increased.

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

Serious Drug Interactions

- Aliskiren-containing drugs if you have diabetes or kidney disease.

The following may interact with CANDESARTAN HCT:

- Adrenocorticotrophic hormone (ACTH), which may be used to treat diseases such as nephrotic syndrome or collagen diseases and in diagnostic tests.
- 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 used to treat the flu and reduce symptoms of Parkinson's Disease .
- Amphotericin B, an antifungal drug.
- Drugs used to treat cancer such as cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs) such as citalopram, escitalopram and sertraline.
- Drugs used to treat diabetes such as insulin and oral medicines.
- Bile acid resins used to lower cholesterol such as cholestyramine.
- Other blood pressure lowering drugs such as:
 - Diuretics ("water pills").
 - Guanethidine.
 - Diazoxide.
 - Methyldopa.
 - Beta-blockers, such as atenolol, metoprolol, propranolol.
 - Vasodilators.
 - Calcium channel blockers, such as felodipine and amlodipine.
 - Angiotensin converting enzyme inhibitors (ACEIs).
 - Angiotensin receptor blockers (ARBs), such as valsartan and losartan.
 - Direct renin inhibitors.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Cyclosporine used to treat autoimmune diseases.
- Digoxin, a heart medication.
- Drugs that slow down or speed up bowel function such as atropine, biperiden, domperidone and metoclopramide.
- Drugs used to treat epilepsy such as carbamazepine and topiramate.
- Gout medications such as allopurinol, probenecid, uricosurics and xanthine oxidase inhibitors.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling such as ibuprofen, naproxen, acetylsalicylic acid and celecoxib.
- Drugs that can increase blood potassium levels such as heparin, co-trimoxazole, potassium supplements or potassium-containing salt substitutes.
- Pressor amines such as norepinephrine.
- Skeletal muscle relaxants used to relieve muscle spasms such as tubocurarine.

How to take CANDESARTAN HCT:

- 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. If CANDESARTAN HCT causes upset stomach, take it with food or milk.
- Swallow CANDESARTAN HCT with a glass of water.
- The package protects each tablet. When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.
- 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 dose:

Your healthcare professional has decided the best dose for you. The recommended dose is 1 tablet once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much CANDESARTAN HCT, contact a healthcare professional, 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 take a double dose.

What are possible side effects from using CANDESARTAN HCT?

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

Side effects may include:

- back or leg pain, muscle cramps, spasms and pain, weakness, restlessness.
- cold or flu-like symptoms.
- dizziness, pins and needles in your fingers, headache.
- urinary tract infections.
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth.
- cough.
- bleeding under skin, rash, red patches on the skin, itching.
- drowsiness, insomnia.
- low sex drive.
- nose bleeds.

CANDESARTAN HCT can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects 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	
COMMON			
Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell.		✓	
Edema: unusual swelling of the arms, hands, legs, ankles or feet.		✓	
High blood sugar: frequent urination, thirst, and hunger.	✓		
Low Blood Pressure: dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up.	✓		
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.		✓	
Tachycardia (abnormally fast heartbeat): dizziness, light-headedness, shortness of breath, racing heart.		✓	
UNCOMMON			
Allergic reactions: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat.		✓	
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue.		✓	

Serious side effects 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	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite.		✓	
RARE			
Acute Respiratory Distress: (inflammation of lung tissue or excess fluid in the lungs): severe shortness of breath or difficulty breathing, fever, weakness, confusion, cough, wheezing, clammy skin, fatigue, blue-tinged lips.			✓
Decreased Platelets: bruising, bleeding, fatigue, weakness, small purple or red dots under the skin.		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms.		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine.		✓	
Vasculitis (inflammation of the blood vessels): fever, confusion, fatigue, unexplained weight loss, sweats, joint or muscle pain or swelling, numbness, tingling, weakness, a rash of bluish purple spots or blotches.			✓
VERY RARE			
Toxic Epidermal Necrolysis (severe skin reaction): redness, blistering and/or severe skin peeling, especially in the mouth and eyes.			✓
UNKNOWN FREQUENCY			
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath.		✓	
Eye disorders: -Choroidal effusion (buildup of			✓

Serious side effects 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	
liquid in your eye): blind spots, eye pain, blurred vision. - Glaucoma : increased pressure in your eyes, eye pain, decrease in vision. - Myopia : sudden near sightedness or blurred vision.			
Lupus (an autoimmune disease that occurs when your body's immune system attacks your own tissues and organs): fever, malaise, joint or muscle pain, fatigue. Conditions may be activated or made worse.		✓	
Pancreatitis (inflammation of the pancreas): abdominal pain that lasts and gets worse when you lie down, nausea, vomiting.		✓	

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 (<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.

Storage:

- Keep in the original package at room temperature (15°C to 30°C) and in a dry place. Do not keep CANDESARTAN HCT in the bathroom.
- Do not keep or use CANDESARTAN HCT after the expiry date indicated on the package. Return any unused medicines, which you know you will no longer need, to your pharmacy for disposal.

Keep out of reach and sight of children.

If you want more information about CANDESARTAN HCT:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare 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> or the manufacturer's website www.sivem.ca or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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