

PART III: CONSUMER INFORMATION

**Pr_rpms-CANDESARTAN
Candesartan cilexetil tablets**

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

ABOUT THIS MEDICATION

What the medication is used for:

pms-CANDESARTAN is used to treat:

- High Blood Pressure in Adults
- High Blood Pressure in Children (6 to 17 years of age)
- Heart Failure in Adults

What it does:

pms-CANDESARTAN is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking pms-CANDESARTAN regularly even if you feel fine.

Its main action is to relax the arteries, letting the blood flow more freely, thereby lowering the blood pressure.

When it should not be used:

Do not take pms-CANDESARTAN if you:

- Are allergic to candesartan cilexetil or to any non-medicinal ingredient in the formulation.
- 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. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.
- Are pregnant or intend to become pregnant. Taking pms-CANDESARTAN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that candesartan cilexetil passes into breast milk.
- Are less than 1 year old.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency

- Glucose-galactose malabsorption
- Because lactose is a non-medicinal ingredient in pms-CANDESARTAN.

What the medicinal ingredient is:

Candesartan cilexetil.

What the non-medicinal ingredients are:

Croscarmellose sodium, hydroxypropyl cellulose, lactose, magnesium stearate, maize starch, red iron oxide (for 8 mg, 16 mg and 32 mg), triethyl citrate.

What dosage forms it comes in:

Tablets: 4 mg, 8 mg, 16 mg and 32 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions- Pregnancy

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

Before you use pms-CANDESARTAN talk to your doctor, nurse or pharmacist if you:

- Have experienced an allergic reaction to any drug used to treat blood pressure, including angiotensin converting enzyme (ACE) inhibitors.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, heart, liver or kidney disease.
- 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” that makes your body keep potassium) or other drugs that may increase potassium levels (e.g., heparin, co-trimoxazole).
- Are on a low-salt diet.
- Are taking a medicine that contains aliskiren, used to lower high blood pressure. The combination with pms-CANDESARTAN is not recommended.
- Are taking an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in “-PRIL”.
- Are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptor antagonists (for example, spironolactone, eplerenone). These medicines are for the treatment of heart failure.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to pms-CANDESARTAN. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

If you are currently taking pms-CANDESARTAN and are going to have an operation, be sure to tell your doctor or dentist about your medication before you are given an anesthetic.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, 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 pms-CANDESARTAN:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, potassium-sparing diuretic (a specific kind of “water pill”, or other drugs that may increase potassium levels (e.g., heparin, co-trimoxazole).
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products or angiotensin converting enzyme (ACE) inhibitors.
- Mineralocorticoid receptor antagonists (for example, spironolactone, eplerenone) and ACE inhibitors used in heart failure.

PROPER USE OF THIS MEDICATION

The dosage of pms-CANDESARTAN is individualized.

Take pms-CANDESARTAN exactly as prescribed. It is recommended to take your dose at about the same time every day.

pms-CANDESARTAN is taken once a day. Even if your doctor has prescribed 2 tablets a day, both should be taken at the same time, unless otherwise indicated.

pms-CANDESARTAN may be taken with food or on an empty stomach but it should be taken consistently the same way each day.

Swallow pms-CANDESARTAN with a glass of water.

Usual Dose:

Lower doses may be required based on the other medications you take and the presence of other disease conditions.

High Blood Pressure in Adults:

Recommended Initial Dose: 16 mg once a day.

Total Daily Dose: 8 mg to 32 mg once a day.

High Blood Pressure in Children (6 to 17 years of age):

- For children who weigh less than 50 kg:
Recommended Starting Dose: 4 mg once a day.
Maximum Dose: 8 mg once a day.
- For children who weigh 50 kg or more:
Recommended Starting Dose: 8 mg once a day.
Maximum Dose: 16 mg once a day.

pms-CANDESARTAN must not be given to children under 1 year of age due to the potential risk to the developing kidneys.

Heart Failure in Adults:

Usual Recommended Initial Dose: 4 mg once a day.

If tolerated by the patient, this dose is gradually doubled (approximately every 2 weeks) until the target dose is reached.

Target Dose: 32 mg once a day.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of pms-CANDESARTAN 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.

Never take a double dose of pms-CANDESARTAN to make up for missed tablets. If you are still unsure, check with your doctor or pharmacist to see what you should do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Dizziness, falls
- drowsiness, insomnia
- rash
- diarrhea, vomiting
- headache
- back or leg pain, muscle cramps
- cough

- sore throat
- dry mouth
- cold symptoms
- pneumonia
- fainting spells
- confusion

Side effects in adults and children are similar, but may occur more often in children.

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

pms-CANDESARTAN 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 emergency medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness	✓		
	Fast, Slow or Irregular Heart Beat	✓		
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
Uncommon	Allergic Reaction: 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.		✓	
	Hematuria (blood in urine)		✓	
	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Shortness of breath, difficulty breathing (Dyspnea, Pulmonary edema)	✓		

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 emergency medical help
		Only if severe	In all cases	
Rare	Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	
Very rare	Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	
Unknown	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea and vomiting		✓	
	Chest Pain		✓	
	Stroke (cerebrovascular accident): face or arm weakness, abnormal speech and blurred vision, loss of consciousness		✓	

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

HOW TO STORE IT

- 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.
- pms-CANDESARTAN tablets are protected in their package, it is best to keep the tablets in their original package at normal room temperature and in a dry place. Do not keep pms-CANDESARTAN in the bathroom.
- **Keep 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 pms-CANDESARTAN 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.

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
 - By calling 1-866-234-2345 (toll-free);
 - By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

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

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing. For the most current information, the Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be obtained by contacting Pharmascience Inc. at 1-888-550-6060.

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