

## PART III: CONSUMER INFORMATION

**Pr** Atacand<sup>®</sup>

(candesartan cilexetil tablets)

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

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

ATACAND 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:**

ATACAND 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 ATACAND 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 ATACAND 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 (such as Rasilez) and you have diabetes or kidney disease.
- Are pregnant or intend to become pregnant. Taking ATACAND during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that ATACAND 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 ATACAND.

#### **What the medicinal ingredient is:**

Candesartan cilexetil.

#### **What the nonmedicinal ingredients are:**

Calcium carboxymethylcellulose, hydroxypropyl cellulose, iron oxide (except 4 mg tablets), lactose, magnesium stearate, maize starch and polyethylene glycol.

#### **What dosage forms it comes in:**

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

### WARNINGS AND PRECAUTIONS

**Serious Warnings and Precautions - Pregnancy  
ATACAND should not be used during pregnancy. If you discover that you are pregnant while taking ATACAND, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.**

Before you use ATACAND talk to your doctor, nurse or pharmacist if you:

- Have experienced an allergic reaction to any drug used to lower 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, such as Rasilez, used to lower high blood pressure. The combination with ATACAND 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 ATACAND. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

**If you are currently taking ATACAND and are going to have an operation, be sure to tell your doctor or dentist about your medication before you are given an anaesthetic.**

### 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 ATACAND:

- 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 (e.g. Rasilez) 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 ATACAND is individualized.

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

ATACAND 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.

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

Swallow ATACAND with a glass of water.

### How to use the blister packs:

- As an aid to help you keep track of your doses, ATACAND comes in a blister pack. The days of the week are printed on the back of the blister. To start, take the tablet that matches the day of the week. Continue taking the tablets in order, until they are all finished.
- There are 14 days of labeled tablets in each blister, with one extra to make 15. All 15 tablets, including the one labeled “Take this tablet last”, are exactly the same. Once you have finished the 14 labeled tablets, take the one marked "Take this tablet last" before starting your next blister pack.

### 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

ATACAND 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 ATACAND 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 ATACAND 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.**

ATACAND 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	√		
	Fast, Slow or Irregular Heart Beat	√		
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		√	

**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	
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)	√		
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		√	

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

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	Only if severe	In all cases	
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 ATACAND, 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.
- ATACAND 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 ATACAND 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 ATACAND 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 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](http://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](http://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**

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 found at:

[www.astrazeneca.ca](http://www.astrazeneca.ca),

or by contacting the sponsor, AstraZeneca Canada Inc. at:  
Customer Inquiries – 1 (800) 668-6000,  
Renseignements – 1 (800) 461-3787.

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