

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ACCUPRIL**®

#### Quinapril (as hydrochloride) tablets

Read this carefully before you start taking **ACCUPRIL** 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 **ACCUPRIL**.

#### Serious Warnings and Precautions

##### Pregnancy

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

#### What is **ACCUPRIL** used for?

- High Blood Pressure (Hypertension): **ACCUPRIL** lowers high blood pressure. It can be used alone or together with a diuretic (“water pill”).
- Congestive Heart Failure: **ACCUPRIL**® is used for congestive heart failure (a condition where the heart is unable to pump enough blood for the body’s needs), when it is combined with either a diuretic (“water pill”) and/or digitalis glycosides (drugs which help the heart beat more normally).

#### How does **ACCUPRIL** work?

**ACCUPRIL** is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’.

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

#### What are the ingredients in **ACCUPRIL**?

Medicinal ingredients: Quinapril hydrochloride

Non-medicinal ingredients: Candelilla wax, crospovidone, gelatin, hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose, magnesium carbonate, magnesium stearate, polyethylene glycol, synthetic red iron oxide, titanium dioxide.

#### **ACCUPRIL** comes in the following dosage forms:

Tablets; 5 mg, 10 mg, 20 mg, 40 mg

**Do not use ACCUPRIL if you:**

- Are allergic to quinapril hydrochloride 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 ACE inhibitor or without a known cause. Be sure to tell your healthcare professional that this has happened to you.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Are taking ENTRESTO™ (sacubitril/valsartan), due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with ACCUPRIL.
- Are pregnant or intend to become pregnant. Taking ACCUPRIL during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. ACCUPRIL passes into breast milk.
- Have renovascular hypertension (a form of high blood pressure that affects the blood vessels leading to the kidney's).
- Are taking aliskiren-containing medicines, such as Rasilez, **and** have one of the following conditions:
  - Diabetes
  - Kidney disease
  - High levels of potassium
  - Congestive heart failure combined with hypotension.
- Are taking an angiotensin receptor blocker (ARB), another medicine to treat your high blood pressure, **and** have one of the following conditions:
  - Diabetes with end organ damage
  - Kidney disease
  - High levels of potassium
  - Congestive heart failure combined with hypotension.

You can recognize ARBs because their medicinal ingredient ends in “-SARTAN”.

- Have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency, a type of lactose intolerance
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in ACCUPRIL.

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

- Are allergic to any drug used to lower blood pressure.
- Have a condition causing your body's immune system to attack your own tissues (collagen vascular disease)

- Have recently received or are planning to get allergy shots for bee or wasp stings.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney problems.
- Are on dialysis or receiving LDL apheresis (treatment to remove “bad cholesterol” from the blood).
- 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”).
- Are taking an antibiotic containing trimethoprim.
- Are on a low-salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Are taking a neutral endopeptidase inhibitor. The combination with ACCUPRIL is not recommended.
- Are taking a medicine that contains aliskiren, such as Rasilez or an angiotensin receptor blocker (ARB). The combination with ACCUPRIL is not recommended.
- Are taking anti-cancer (temsirolimus, everolimus), anti-rejection (sirolimus) or anti-diabetic (gliptins) drugs. Use of ACE inhibitors, such as ACCUPRIL, with these drugs may increase the chance of having an allergic reaction.
- Have a medical history or family history of psoriasis (rash with itchy, scaly patches usually on the knees, elbows truck and scalp).

**Other warnings you should know about:**

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

If you are going to have surgery and will be given an anesthetic, be sure to tell your healthcare professional that you are taking ACCUPRIL.

**Driving and using machines:** Before you perform tasks, which may require special attention, wait until you know how you respond to ACCUPRIL. Dizziness, light-headedness, or fainting can especially occur after the first dose and when the dose is increased. Exercise caution when driving or operating a vehicle or potentially dangerous machinery.

**Development or worsening symptoms of psoriasis:**

ACCUPRIL can cause or worsen psoriasis (rash with itchy, scaly patches usually on the knees, elbows truck and scalp). Talk to your healthcare professional if you experience symptoms of psoriasis or worsening psoriasis.

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

### The following may interact with ACCUPRIL:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill”) or sulfamethoxazole/trimethoprim.
- Alcohol
- Allopurinol used to treat gout.
- Anti-cancer drugs, including cyclophosphamide, methotrexate and temsirolimus and everolimus
- Anti-rejection drugs, such as sirolimus (Rapamune)
- Anti-diabetic drugs including insulin and oral medicines (e.g. metformin, gliptins, sulfonylureas)
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), angiotensin receptor blockers (ARBs) (in addition to ACCUPRIL)
- Gold for the treatment of rheumatoid arthritis.
- Lithium used to treat bipolar disease
- Neutral endopeptidase (NEP) inhibitor used to treat heart failure
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Tetracycline (a type of antibiotic)

### How to take ACCUPRIL:

#### Usual dose:

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

#### Usual Adult Dose:

##### High Blood Pressure (Hypertension)

**For patients NOT taking a diuretic (“water pills”):** The recommended starting dose is 10 mg once a day.

**For patients ALSO taking a diuretic (“water pill”):** The recommended starting dose is 5 mg once a day.

##### Congestive Heart Failure

The recommended starting dose is 5 mg once a day.

#### Overdose:

If you think you, or a person you are caring for, have taken too much ACCUPRIL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have forgotten to take your dose during the day, take it as soon as you remember. If it is almost time for the next dose, the missed dose should be skipped. You carry on with the next dose at the usual time. Do NOT double dose.

**What are possible side effects from using ACCUPRIL?**

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

Side effects may include:

- Dizziness, headache, trouble sleeping
- drowsiness, fatigue, weakness
- cough, stuffy and runny nose
- abdominal pain, diarrhea, indigestion, nausea, vomiting
- back pain

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

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
<b>Low blood pressure:</b> dizziness, fainting, light-headedness  May occur when you go from lying or sitting to standing up.	✓		
<b>Increased levels of potassium in the blood:</b> irregular heartbeat, muscle weakness and generally feeling unwell		✓	
<b>UNCOMMON</b>			
<b>Allergic reaction, including angioedema:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
<b>Kidney disorder:</b> 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
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<b>Liver disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
<b>Electrolyte imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
<b>Tachycardia:</b> fast heartbeat		✓	
<b>Edema:</b> swelling of hands, ankles or feet		✓	
Rash, red patches on skin, including a skin disorder called psoriasis	✓		
<b>RARE</b>			
<b>Decreased platelets:</b> bruising, bleeding, fatigue and weakness		✓	
<b>Decreased white blood cells:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
<b>Chest Pain, heart attack</b>			✓
<b>Shortness of breath</b>	✓		
<b>Coughing up blood</b>			✓
<b>High nitrogen compound found in blood (Azotemia):</b> rapid heart rate, high blood pressure, fatigue, confusion, light headedness, dizziness, decreased urine production			✓

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:**

Store ACCUPRIL at room temperature, between 15° and 30°C. Protect from moisture. Keep in well closed container.

Keep out of reach and sight of children.

### **If you want more information about ACCUPRIL**

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>; the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.
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