

PART III: CONSUMER INFORMATION**Pr**QUINAPRIL
Quinapril Tablets, USP

This leaflet is part III of a three-part "Product Monograph" published when QUINAPRIL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about QUINAPRIL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:****High Blood Pressure (Hypertension)**

QUINAPRIL lowers high blood pressure. It can be used alone or together with a diuretic ("water pill").

Congestive Heart Failure

QUINAPRIL 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).

What it does:

QUINAPRIL 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 QUINAPRIL regularly even if you feel fine.

When it should not be used:

Do not take QUINAPRIL if you:

- Are allergic to quinapril hydrochloride or to any nonmedicinal 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 doctor, nurse, or pharmacist 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 pregnant or intend to become pregnant. Taking QUINAPRIL during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. QUINAPRIL passes into breast milk.

- Have type 1 or type 2 diabetes or kidney problems and are taking medicine containing aliskiren
- Have renovascular hypertension (a form of high blood pressure that affects the blood vessels leading to the kidney's).
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorptionBecause lactose is a non-medicinal ingredient in QUINAPRIL.

What the medicinal ingredient is:

Quinapril hydrochloride

What the nonmedicinal ingredients are:

crospovidone, gelatin powder, iron oxide red, iron oxide yellow, lactose, polyethylene glycol, magnesium carbonate, magnesium stearate, polyvinyl alcohol, titanium dioxide.

What dosage forms it comes in:

Tablets: 5 mg, 10 mg, 20 mg and 40 mg

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions - Pregnancy**

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

BEFORE you use QUINAPRIL talk to your doctor, nurse, or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- 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 disease.
- 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 on a low-salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Are taking Aliskiren-containing medicines. Use of QUINAPRIL with these medicines is not recommended
- Are taking anti-cancer (temsirolimus, everolimus), anti-rejection (sirolimus) or anti-diabetic (gliptins) drugs. Use of

ACE inhibitors, such as QUINAPRIL, with these drugs may increase the chance of having an allergic reaction.

You may become sensitive to the sun while taking QUINAPRIL. 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 doctor or dentist that you are taking QUINAPRIL.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to QUINAPRIL. 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, 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 QUINAPRIL:
Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”) or aliskiren. Use of QUINAPRIL with these medicines is not recommended.

- Alcohol
- Allopurinol used to treat gout.
- Anti-cancer drugs (e.g. temsirolimus and everolimus)
- Anti-rejection drugs, such as sirolimus
- Antidiabetic drugs, including insulin and oral medicines.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics (“water pills”). When taken in combination with QUINAPRIL, they may cause excessively low blood pressure.
- Tetracycline (a type of antibiotic)

PROPER USE OF THIS MEDICATION

Take QUINAPRIL 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 have taken too much QUINAPRIL contact your doctor, nurse, pharmacist, 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, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dizziness
- drowsiness, fatigue, weakness
- cough
- rash, itching
- headache
- abdominal pain
- nausea, vomiting, diarrhea
- indigestion
- stuffy, runny nose
- back pain
- trouble sleeping

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

QUINAPRIL 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 or pharmacist		Stop taking drug and seek immediate emergency medical attention
	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.	✓	
	Increased levels of potassium in the blood: Irregular heartbeat, 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		✓
	Liver disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓
	Electrolyte imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓
	Tachycardia: Fast heart beat		✓
	Edema: Swelling of hands, ankles or feet		✓
	Decreased platelets: bruising, bleeding, fatigue and weakness		✓
Rare	Decreased white blood cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓
	Chest Pain		✓
	Shortness of breath	✓	
	Coughing up blood		✓

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

HOW TO STORE IT

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

Keep QUINAPRIL out of the reach and sight of children.

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, Ontario
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 Pro Doc Ltée at 1-800-361-8559, www.prodqc.ca or info@prodqc.ca.

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Last revised: November 22, 2013