

PART III: CONSUMER INFORMATION

GD-quinapril
(quinapril hydrochloride tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:

High Blood Pressure (Hypertension)

GD-quinapril lowers high blood pressure. It can be used alone or together with a diuretic (“water pill”).

Congestive Heart Failure

GD-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:

GD-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 GD-quinapril regularly even if you feel fine.

When it should not be used:

Do not take GD-quinapril 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 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 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 GD-quinapril.
- Are pregnant or intend to become pregnant. Taking GD-quinapril during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. GD-quinapril 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, or another ACE inhibitors **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
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in GD-quinapril.

What the medicinal ingredient is:

Quinapril hydrochloride

What the nonmedicinal ingredients are:

Candelilla wax, crosopovidone, gelatin, hydroxypropylcellulose, hydroxypropylmethylcellulose, lactose, magnesium carbonate, magnesium stearate, polyethylene glycol, synthetic red iron oxide, titanium dioxide.

What dosage forms it comes in:

Tablets; 5, 10, 20, 40 mg

WARNINGS AND PRECAUTIONS

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

BEFORE you use GD-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 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 GD-quinapril is not recommended.
- Are taking a medicine that contains aliskiren, such as Rasilez, an angiotensin receptor blocker (ARB) or another ACE inhibitor (in addition to GD-quinapril). The combination with GD-quinapril is not recommended.
- Are taking anti-cancer (temsirolimus, everolimus), anti-rejection (sirolimus) or anti-diabetic (gliptins) drugs. Use of ACE inhibitors, such as GD-quinapril, with these drugs may increase the chance of having an allergic reaction.

You may become sensitive to the sun while taking GD-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 GD-quinapril.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to GD-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 GD-quinapril:

- 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) or other ACE inhibitors (in addition to GD-quinapril).
- Gold for the treatment of rheumatoid arthritis.
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Tetracycline (a type of antibiotic)

PROPER USE OF THIS MEDICATION

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

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

GD-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, nurse or pharmacist		Stop taking drug and seek immediate medical help
		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, including angioedema: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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	
	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		√	
	Rare	Decreased platelets: bruising, bleeding, fatigue and weakness		√

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	
Decreased white blood cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
Chest Pain , heart attack			√
Shortness of breath	√		
Coughing up blood			√
High nitrogen compound found in blood (Azotemia): rapid heart rate, high blood pressure, fatigue, confusion, lightheadedness, dizziness, decreased urine production			√

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

HOW TO STORE IT

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

Keep GD-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 found at: <http://www.Pfizer.ca> or by contacting the sponsor, GenMed, a division of Pfizer Canada Inc., at: 1-800-463-6001

This leaflet was prepared by GenMed, a division of Pfizer Canada Inc.

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