

PART III: CONSUMER INFORMATION**ACCURETIC®****(quinapril hydrochloride and hydrochlorothiazide tablets)**

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

ABOUT THIS MEDICATION**What the medication is used for:**

ACCURETIC® lowers high blood pressure.

What it does:

ACCURETIC® contains a combination of 2 drugs, quinapril hydrochloride and hydrochlorothiazide:

- Quinapril hydrochloride is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in “PRIL”. It lowers blood pressure.
- Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking ACCURETIC® regularly even if you feel fine.

When it should not be used:

Do not take ACCURETIC® if you:

- Are allergic to quinapril hydrochloride or hydrochlorothiazide or to any non-medicinal ingredients in the formulation
- Are allergic to any sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”
- 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 ACCURETIC®.
- Have difficulty urinating or produce no urine
- Are pregnant or intend to become pregnant. Taking ACCURETIC® during pregnancy can cause injury and even death to your baby
- Are breastfeeding. ACCURETIC® passes into breast milk.
- 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 inhibitor **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 ACCURETIC.

What the medicinal ingredient is:

Quinapril hydrochloride and hydrochlorothiazide

What the non-medicinal ingredients are:

Candelilla wax, crospovidone, lactose, magnesium carbonate, magnesium stearate, povidone, synthetic red iron oxide, synthetic yellow iron oxide and titanium oxide.

What dosage forms it comes in:

Tablets:

10 mg quinapril hydrochloride and 12.5 mg hydrochlorothiazide
 20 mg quinapril hydrochloride and 12.5 mg hydrochlorothiazide
 20 mg quinapril hydrochloride and 25 mg hydrochlorothiazide

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

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

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

- Are allergic to any drug used to lower blood pressure or penicillin
- 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
- Have lupus or gout
- 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 ACCURETIC® is not recommended.
- Are taking an aliskiren-containing medicine, such as Rasilez, used to lower high blood pressure. The combination with ACCURETIC is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”
- Are taking a medicine that contains aliskiren, such as Rasilez, an angiotensin receptor blocker (ARB), or another ACE inhibitor (in addition to ACCURETIC). The combination with ACCURETIC is not recommended.
- Are currently taking anti-cancer (temsirolimus, everolimus), anti-rejection (sirolimus) or anti-diabetic (gliptins) drugs. Use of ACE inhibitors, such as ACCURETIC, with these drugs may increase the chance of having an allergic reaction.
- Have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Risk of skin cancer:

- ACCURETIC contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking ACCURETIC for many years (more than 3) or at a high dose.
- While taking ACCURETIC:
 - Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
 - Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
 - Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

Hydrochlorothiazide in ACCURETIC® can cause sudden eye disorders:

- **Choroidal effusion:** an abnormal buildup of liquid behind the white outer layer of your eye that may result in vision changes.
- **Myopia:** sudden nearsightedness or blurred vision
- **Glaucoma:** an increased pressure in your eye, eye pain. Untreated, it may lead to permanent vision loss

If your vision changes, stop taking ACCURETIC and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting ACCURETIC®

You may become sensitive to the sun while taking ACCURETIC®. 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 ACCURETIC®.

Driving and using machines: before you perform tasks which may require special attention, wait until you know how you respond to ACCURETIC®. 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 the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with ACCURETIC®:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome
- Alcohol, narcotics (strong pain medications) or barbiturates (sleeping pills). They may cause low blood pressure and dizziness when you go from lying down or sitting to standing up.
- Amphotericin B, an antifungal drug
- Anti-cancer drugs, including cyclophosphamide, methotrexate, temsirolimus and everolimus
- Anti-rejection drugs, such as sirolimus (Rapamune)
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline
- Anti-diabetic drugs including insulin and oral medicines (e.g. metformin, gliptins, sulfonylureas)
- Bile acid resins used to lower cholesterol
- Calcium or vitamin D supplements
- Corticosteroids used to treat joint pain and swelling
- Digoxin, a heart medication
- Drugs known to increase the potassium level in the blood such as a salt substitute that contains potassium, potassium supplements, potassium-sparing diuretic (a specific kind of “water pill”) (e.g. spironolactone, triamterene, amiloride, sulfamethoxazole/trimethoprim).
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide, and domperidone
- Drugs used to treat epilepsy, including carbamazepine and topiramate
- Gold for the treatment of rheumatoid arthritis
- Gout medications, including allopurinol and probenecid
- Lithium used to treat bipolar disease
- Non-steroidal 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), angiotensin receptor blockers (ARBs) or other ACE inhibitors (in addition to ACCURETIC).
- Pressor amines (drugs which increase blood pressure, such as adrenaline)
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurane
- Tetracycline (a type of antibiotic)

ACCURETIC® 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

Table 1 – 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 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	√		
	Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		√	
Common	Non-melanoma skin cancer: lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		√	

PROPER USE OF THIS MEDICATION

ACCURETIC is not for initial therapy. You must first be stabilized on the individual medicinal ingredients (quinapril hydrochloride and hydrochlorothiazide) of ACCURETIC. If your dosage matches the dosages in ACCURETIC, your doctor may prescribe ACCURETIC taken once a day (instead of each medicinal ingredient as a separate pill).

Take ACCURETIC® exactly as prescribed. It is recommended to take your dose at about the same time every day. ACCURETIC® can be taken with or without food. If ACCURETIC® causes upset stomach, take it with food or milk.

Usual Adult dose:

The recommended starting dose is one 10 mg/12.5 mg tablet daily.

Overdose:

If you think you have taken too much ACCURETIC® 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, upset stomach, decreased appetite, constipation,
- Muscle pain, spasms, back pain , restlessness
- Pins and needles in your fingers
- Nausea, vomiting, diarrhea
- Sore throat
- Stuffy, runny nose
- Reduced libido
- Rash, red patches on the skin

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

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

Table 1 – 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 medical help
	Only if severe	In all cases	
Uncommon	Allergic reaction including angioedema rash, hives. Swelling of the face, lips, tongue or throat, difficulty swallowing or breathing		√
			√
			√
			√
Uncommon	Increased blood sugar: frequent urination, thirst and hunger	√	
			√
			√
Rare	Decreased platelets: Bruising, bleeding, fatigue and weakness		√

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

Table 1 – 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 medical help
	Only if severe	In all cases	
	Decreased white blood cells: Infections, fatigue, fever, aches, pains and flu-like symptoms		√
			√
Very rare	Toxic epidermal necrolysis: Severe skin peeling, especially in the mouth and eyes		√

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

Table 1 – 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 medical help
		Only if severe	In all cases	
Unknown	Eye disorders: Choroidal effusion: blind spots, eye pain, blurred vision Myopia: sudden near sightedness or blurred vision Glaucoma: Increased pressure in your eyes, eye pain			√
	Anemia: fatigue, loss of energy, weakness, shortness of breath		√	
	Inflammation of the pancreas: Abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		√	
	Tachycardia: Fast heart beats		√	

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

HOW TO STORE IT

Store ACCURETIC® at room temperature, between 15° and 25°C. Protect from moisture. Keep in well closed container. Keep ACCURETIC® 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 <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- 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 1908C
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 <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

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, Pfizer Canada ULC, at: 1-800-463-6001

This leaflet was prepared by Pfizer Canada ULC

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