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
- 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 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.

**Hydrochlorothiazide in ACCURETIC® can cause sudden eye disorders:**

- **Myopia:** sudden nearsightedness or blurred vision
- **Glaucoma:** an increased pressure in your eye, eye pain. Untreated, it may lead to permanent vision loss

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®:

- Adrenocorticotropic 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 tubocurare
- Tetracycline (a type of antibiotic)

**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.

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>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and seek immediate medical help</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decreased or increased levels of potassium in the blood:</strong> irregular heartbeats, muscle weakness and generally feeling unwell</td>
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<tr>
<td><strong>Low blood pressure:</strong> dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up</td>
<td>Only if severe</td>
<td>In all cases</td>
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<tr>
<td><strong>Allergic reaction including angioedema rash, hives. Swelling of the face, lips, tongue or throat, difficulty swallowing or breathing</strong></td>
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<td><strong>Kidney disorder:</strong> decreased urination, nausea, vomiting, swelling of extremities, fatigue</td>
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<td><strong>Liver disorder:</strong> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite</td>
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<tr>
<td><strong>Increased blood sugar:</strong> frequent urination, thirst and hunger</td>
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<td>Electrolyte imbalance: Weakness, drowsiness, muscle pain or cramps, irregular heartbeat</td>
<td>Only if severe</td>
<td>√</td>
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<tr>
<td>Rare</td>
<td></td>
<td>In all cases</td>
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<tr>
<td>Decreased platelets: Bruising, bleeding, fatigue and weakness</td>
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<tr>
<td>Decreased white blood cells: Infections, fatigue, fever, aches, pains and flu-like symptoms</td>
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<td>Edema: Swelling of the hands, ankles or feet</td>
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<td>Vomiting blood</td>
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<tr>
<td>High nitrogen compound found in blood (Azotemia): rapid heart rate, high blood pressure, fatigue, confusion, lightheadedness, dizziness, decreased urine production</td>
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<td>Chest Pain Heart attack</td>
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<td>Very rare</td>
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<tr>
<td>Toxic epidermal necrolysis: Severe skin peeling, especially in the mouth and eyes</td>
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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°C 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 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, Pfizer Canada Inc., at:
1-800-463-6001

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