

## **PATIENT MEDICATION INFORMATION**

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

#### **Pr ACCURETIC**

#### **Quinapril (as 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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ACCURETIC**.

#### **Serious Warnings and Precautions- Pregnancy**

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

#### **What is ACCURETIC used for?**

ACCURETIC lowers high blood pressure.

#### **How does ACCURETIC work?**

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.

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

Medicinal ingredients: Quinapril hydrochloride and hydrochlorothiazide

Non-medicinal ingredients: Candelilla wax, crospovidone, lactose, magnesium carbonate, magnesium stearate, povidone, synthetic red iron oxide, synthetic yellow iron oxide and titanium oxide.

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

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

### **Do not use ACCURETIC if:**

Do not take ACCURETIC if you:

- Are allergic to quinapril hydrochloride or hydrochlorothiazide or to any non-medicinal ingredients in the formulation
- Have a condition causing your body's immune system to attack your own tissues (collagen vascular disease)
- 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 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 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, **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.

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

- Are allergic to any drug used to lower blood pressure or penicillin
- 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
- 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, or an angiotensin receptor blocker (ARB). 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.
- Have a medical history or family history of psoriasis (rash with itchy, scaly patches usually on the knees, elbows, trunk and scalp).
- Have had breathing or lung problems (including inflammation or fluid in the lungs) in the past following the use of medication containing hydrochlorothiazide. If you

experience any severe shortness of breath or difficulty breathing after taking ACCURETIC, stop the medication and seek medical attention immediately.

### **Other warnings you should know about:**

#### **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 healthcare professional 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 healthcare professional 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, 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.

#### **Hydrochlorothiazide in ACCURETIC can cause sudden respiratory toxicity, called Acute Respiratory Distress Syndrome (ARDS)**

- Treatment with hydrochlorothiazide can lead to pulmonary edema, accumulation of fluid in lungs, within minutes to hours after taking the medicine.
- Talk to your healthcare professional immediately if you experience sudden onset in difficulty or labored breathing, fever, and low blood pressure (e.g. dizziness or light-headedness). Stop taking ACCURETIC and seek immediate medical help.

**Development or worsening symptoms of psoriasis:**

ACCURETIC can cause or worsen psoriasis. Speak 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 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 monoamine oxidase inhibitors (MAOI) or 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
- Chronic heart failure drugs such as Entresto (sacubitril / valsartan)
- 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
- Drugs that lower blood sugar such as DDP-IV inhibitors (linagliptin, saxagliptin, sitagliptin).
- Gold for the treatment of rheumatoid arthritis
- Gout medications, including allopurinol and probenecid
- Lithium used to treat bipolar disease
- Neutral endopeptidase (NEP) inhibitors used to treat heart failure

- 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).
- Pressor amines (drugs which increase blood pressure, such as adrenaline)
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine
- Tetracycline (a type of antibiotic)

**How to take Accuretic:**

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 healthcare professional 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, or a person you are caring for, have taken too much ACCURETIC, 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 ACCURETIC?**

These are not all the possible side effects you may have when taking ACCURETIC. 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
- 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

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

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<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>Decreased or increased levels of potassium in the blood:</b> irregular heartbeats, muscle weakness and generally feeling unwell		✓	
<b>Non-melanoma skin cancer:</b> 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.		✓	
<b>UNCOMMON</b>			
<b>Allergic reaction including;</b> angioedema rash, hives. Swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
<b>Kidney disorder:</b> decreased urination, nausea, vomiting, swelling of extremities, fatigue		✓	
<u>Liver disorder:</u> yellowing of the skin or eyes, dark urine,		✓	

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
abdominal pain, nausea, vomiting, loss of appetite			
<b>Increased blood sugar:</b> frequent urination, thirst, and hunger	✓		
<b>Electrolyte imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
<b>Fever</b>		✓	
<b>Shortness of breath</b>			✓
<b>Rash, red patches on skin, including psoriasis</b>	✓		
<b>RARE</b>			
<b>Decreased platelets:</b> bruising, bleeding, fatigue, and weakness		✓	
<u>Decreased white blood cells:</u> infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
<u>Edema:</u> Swelling of the hands, ankles or feet		✓	
<b>Vomiting 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			✓
<b>Chest Pain</b> <b>Heart attack</b>			✓

<b>VERY RARE</b>			
<b>Toxic epidermal necrolysis:</b> severe skin peeling, especially in the mouth and eyes			✓
<b>Acute Respiratory Distress Syndrome (ARDS):</b> <b><u>(inflammation of lung tissue or excess fluid in the lungs):</u></b> Severe difficulty breathing, including shortness of breath, fever, weakness, and confusion.			
<b>UNKNOWN</b>			
<b>Eye disorders:</b> <b>Choroidal effusion:</b> blind spots, eye pain, blurred vision <b>Myopia:</b> sudden near sightedness or blurred vision <b>Glaucoma:</b> Increased pressure in your eyes, eye pain			✓
<b>Anemia:</b> fatigue, loss of energy, weakness, shortness of breath		✓	
<b>Inflammation of the pancreas:</b> abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
<b>Tachycardia:</b> Fast heart beats		✓	

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 ACCURETIC at room temperature, between 15° and 25°C. Protect from moisture. Keep in well closed container.

Keep out of reach and sight of children.

**If you want more information about ACCURETIC:**

- 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

This leaflet was prepared by Pfizer Canada ULC.

Last Revised 13 December 2022