

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr **BENAZEPRIL**

Benazepril Hydrochloride tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

BENAZEPRIL lowers high blood pressure.

What it does:

BENAZEPRIL is an angiotensin converting enzyme (ACE) inhibitors. 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 BENAZEPRIL regularly even if you feel fine.

When it should not be used:

Do not take BENAZEPRIL if you:

- Are allergic to BENAZEPRIL or to any of the other 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 any other medication, including medications for blood pressure, 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 BENAZEPRIL during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. BENAZEPRIL passes into breast milk.
- Are already taking a blood pressure- lowering medicine that contains aliskiren (such as RASILEZ) and you have diabetes or kidney disease.

What the medicinal ingredient is:

Benazepril hydrochloride.

What the important nonmedicinal ingredients are:

BENAZEPRIL tablets contain the following inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, microcrystalline cellulose, polyethylene glycol, red iron oxide (20 mg only) titanium dioxide, yellow iron oxide (5 mg and 10 mg only) and zinc stearate.

What dosage forms it comes in:

BENAZEPRIL is available as 5 mg, 10 mg and 20 mg tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions-Pregnancy

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

Before taking BENAZEPRIL, 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 liver or kidney disease.
- Have diabetes.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are on dialysis.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of öwater pillö),
- Are on a low-salt diet,
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Have collagen vascular diseases. Collagen vascular diseases are (diseases in which the body reacts against its own tissues, often causing joint pain and inflammation). Examples are systemic lupus erythematosus or scleroderma.

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- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with BENAZEPRIL is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in -SARTAN.
- Are taking medicine to treat some cancer and non-cancerous growths associated with genetic disorders (e.g. temsirolimus, sirolimus, everolimus).
- Cyclosporine, an immunosuppressant medicine used in transplanted patients to reduce the risk of organ rejection.
- Heparin, an anticoagulant medicine used to prevent or treat blood clots.
- Erythropoietin, a medicine used to regulate the production of red blood cells.
- Gold for the treatment of rheumatoid arthritis.
- Medicine used to treat some cancers and also some non-cancerous growths associated with a genetic disorder (e.g. temsirolimus, sirolimus, everolimus)

You may become sensitive to the sun while taking BENAZEPRIL. 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 BENAZEPRIL.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to BENAZEPRIL. Dizziness, lightheadedness, or fainting can occur. Take care especially 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 BENAZEPRIL:

- 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).
- Alcohol as it may make blood pressure fall more and/or increase the possibility of dizziness or fainting.
- Antidiabetic drugs, including insulin, oral medicines and dipeptidyl peptide-IV inhibitors.
- Gout medications, including allopurinol and probenecid.
- Lithium used to treat bipolar disease and other psychological conditions.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, indomethacin and celecoxib.
- Other blood pressure lowering drugs, including diuretics (water pills), angiotensin receptor blockers ARBs or aliskiren-containing products (e.g. RASILEZ).

PROPER USE OF THIS MEDICATION

Take BENAZEPRIL exactly as prescribed. It is recommended to take your dose at about the same time every day.

You can take BENAZEPRIL before, during or after a meal since food will not decrease its effectiveness. Swallow your tablet with a glass of water.

The dose of BENAZEPRIL must be individualized. Your doctor will prescribe the lowest possible dose for your needs, to be taken once or twice a day. Your doctor will tell you exactly how many tablets of BENAZEPRIL to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Do not exceed the recommended dose. Never change the dose unless told to do so.

Usual Adult Dose:

Recommended Initial Dose: 10 mg a day.

Usual Maintenance Dose: 20 mg a day.

Maximum Dose: 40 mg a day.

In patients with severe kidney disease:

Recommended Initial Dose: 5 mg a day.

Overdose:

If you think you have taken too much BENAZEPRIL contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of this medicine, take the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and then take the next one at the usual time. Do not take a double dose on the next day to make up for the forgotten tablet(s).

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dizziness;
- drowsiness, fatigue, weakness;
- cough (dry, non-productive, mainly at night, continuing);
- sore throat and throat irritation;
- headache;
- abdominal pain; pain in your muscles, back or bones,
- rash, itching, increased sensitivity of the skin to sun, flushing;
- diarrhea, constipation, vomiting, nausea, stomach upset ;
- numbness or tingling in the hands, feet or lips;
- ringing in the ears;
- loss of taste;
- erectile dysfunction;

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

BENAZEPRIL 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 medical help
	Only if severe	In all cases	
Common		☺	
Increased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell		☺	

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, sore throat, aches, pains, and flu-like symptoms		☺	
Uncommon		☺	
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		☺	
Allergic Reactions, (Angiodema): Rash, hives, swelling of the face, eyes, lips or tongue, throat, arms or legs, or trouble swallowing or breathing			☺
Low Blood Pressure: Dizziness, light-headedness, fainting. May occur when you go from lying or sitting to standing up.		☺	
Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting			☺

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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	
Liver Disorder: Yellowing of the skin or eyes, abdominal pain, nausea, vomiting, loss of appetite, dark urine.		☺	
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities fatigue		☺	
Stroke: numbness, tingling, weakness on one side of your body, vision changes, trouble speaking, walking or with balance, confusion, and severe headache			☺
Depression: Sad mood, nervousness, sleep problems, tiredness	☺		
Respiratory Problems: Shortness of breath, trouble breathing, wheezing		☺	

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	
Heart Attack: Sudden crushing chest pain, , fast or irregular heartbeat, shortness of breath			☺
Stevens-Johnson Syndrome: Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever			☺
Anemia: fatigue, loss of energy, weakness, shortness of breath		☺	
Decreased Platelets: bruising, spontaneous bleeding, fatigue and weakness		☺	
Hypoglycemia: (low blood sugars in diabetic patients): nervousness, sweating, trembling, weakness, palpitations	☺		
Vision problems: Blurred or decreased vision, temporary loss of vision, seeing in a distorted manner			☺

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

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HOW TO STORE IT

All medicines should be kept out of the reach of children. BENAZEPRIL should be stored in its original package at room temperature, in a dry place and out of direct light. The expiry date of this medicine is printed on the package label. Do not use the medicine after this date. If your doctor tells you to stop taking BENAZEPRIL or you find that they have passed their expiry date, please return any left over medicine to your pharmacist.

Store at room temperature (15°C - 30°C).

REPORTING SUSPECTED 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, AA Pharma Inc. at:

1-877-998-9097

This leaflet was prepared by AA Pharma Inc.

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