

Part III : CONSUMER INFORMATION**Pr LOTENSIN®
benazepril hydrochloride tablets**

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

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

LOTENSIN lowers high blood pressure.

What it does:

LOTENSIN 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 LOTENSIN regularly even if you feel fine.

When it should not be used:

Do not take LOTENSIN if you:

- Are allergic to benazepril hydrochloride or to any 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 LOTENSIN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. LOTENSIN 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.
- If you have severe lactose intolerance or one of the following rare hereditary diseases:
 - Galactose intolerance

- Lapp lactase deficiency
 - Glucose-galactose malabsorption
- Because lactose (milk sugar) is a non-medicinal ingredient in LOTENSIN.

What the medicinal ingredient is:

Benazepril hydrochloride.

What the nonmedicinal ingredients are:

Cellulose compounds, colloidal silicon dioxide, corn starch, crospovidone, hydrogenated castor oil, iron oxide, lactose, polyethylene glycol, talc and titanium dioxide.

What dosage forms it comes in:

Tablets 5 mg and 20 mg.

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

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

BEFORE you use LOTENSIN 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 “water pill”),
- 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.
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with LOTENSIN 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).

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

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

- 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).
- 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)

PROPER USE OF THIS MEDICATION

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

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

The dose of LOTENSIN 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 LOTENSIN 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 LOTENSIN 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).

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.

LOTENSIN 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 | | ✓ | |
| | Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms | | ✓ | |
| Uncommon | Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat | | ✓ | |

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| Allergic Reactions, (Angioedema): 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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|--|-------------------------------------|--------------|--|
| | 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 | | | ✓ |

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| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and seek immediate medical help |
|--|-------------------------------------|--------------|--|
| | Only if severe | In all cases | |
| Depression: Sad mood, nervousness, sleep problems, tiredness | ✓ | | |
| Respiratory Problems: Shortness of breath, trouble breathing, wheezing | | ✓ | |
| 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 | | ✓ | |

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| Symptom / effect | Talk with your doctor or pharmacist | | Stop taking drug and seek immediate medical help |
|---|-------------------------------------|--------------|--|
| | Only if severe | In all cases | |
| 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 LOTENSIN, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

- Store between 15°C and 30°C. Protect from moisture and heat.
- **Keep out of the reach and sight of children.**
- Do not use after the expiry date shown on the box.

- Store in the original package.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.
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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

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.novartis.ca>

or by contacting the sponsor,
 Novartis Pharmaceuticals Canada Inc., at:
 1-800-363-8883