IMPORTANT: PLEASE READ

PART III CONSUMER INFORMATION

ZESTRIL®

(lisinopril tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:

Your doctor has prescribed you ZESTRIL for one of the following reasons:

- Your blood pressure is too high (hypertension);
- You have a heart condition known as heart failure, where the heart does not pump your blood around your body as well as it should;
- You have had a heart attack (myocardial infarction) that may lead to a weakening of the heart. ZESTRIL slows the weakening down.

What it does:

ZESTRIL 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 ZESTRIL regularly even if you feel fine.

ZESTRIL works by widening your blood vessels, which helps reduce your blood pressure and makes it easier for your heart to pump blood to all parts of your body.

When it should not be used:

Do not take ZESTRIL if you:

- Are allergic to lisinopril or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with itching, hives, feeling dizzy, 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 ZESTRIL.
- Are pregnant or intend to become pregnant. Taking ZESTRIL during pregnancy can cause injury or even death to your baby.
- Are breastfeeding. ZESTRIL passes into breast milk.
- Are already taking a blood pressure-lowering medicine containing aliskiren (such as Rasilez) and you have one of the following conditions:
    - diabetes
    - kidney disease
    - high potassium levels
    - heart failure combined with low blood pressure
- 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 potassium levels
    - heart failure combined with low blood pressure

  You can recognize ARBs because their medicinal ingredient ends in "**-SARTAN**".
- Are less than 6 years old.
- Are 6 to 16 years old with severe kidney problems.

What the medicinal ingredient is:

lisinopril dihydrate

What the non-medicinal ingredients are:

calcium hydrogen phosphate, magnesium stearate, maize starch, mannitol, pregelatinised starch, and red iron oxide.

What dosage form it comes in:

ZESTRIL tablets are supplied in 3 strengths: 5 mg, 10 mg and 20 mg. The tablets are pink and are available in bottles containing 100 tablets.

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions - Pregnancy

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

Before you use ZESTRIL 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 diabetes, liver or kidney disease.
- Are on dialysis.
- 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 on a low-salt diet.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with ZESTRIL is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "**-SARTAN**".
- Are receiving gold (sodium aurothiomalate) injections.
- Are taking drugs such as:
    - Temsirolimus and everolimus (used to treat cancer),
    - Sirolimus (used to prevent organ rejection after a transplant),
    - A neutral endopeptidase inhibitor.

      Taking ACE inhibitors, such as ZESTRIL with these types of drugs may increase your chances of having an allergic reaction (angioedema).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

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

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

The following may interact with ZESTRIL:

- 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").
- Allopurinol used to treat gout.
- Drugs to treat diabetes such as:
    - Insulin,
    - Oral medications (such as sulphonylureas).

      Your dose of these types of drugs may need to be changed when taking them in combination with ZESTRIL.
- Temsirolimus and everolimus (drugs to treat cancer).
- Gold for the treatment of rheumatoid arthirits.
- Lithium used to treat bipolar disease.
- Non-steroidal anti-inflammatory medicines (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), or angiotensin receptor blockers (ARBs).

- Sirolimus, a drug used to prevent the organ rejection after a transplant.

- Tissue plasminogen activator (tPA) that is used to dissolve blood clots that have formed in blood vessels.

PROPER USE OF THIS MEDICATION

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

Swallow the tablet with a drink of water. It does not matter if you take ZESTRIL before or after food.

Do not stop taking your tablets if you are feeling well, unless your doctor tells you.

Usual dose:

Adults

High blood pressure: the usual recommended starting dose is 10 mg taken once daily.

Heart failure: the usual recommended starting dose is 2.5 mg taken once a day. The usual long-term dose is 5 to 35 mg taken once daily.

Following a heart attack: the usual recommended starting dose is 5 mg on day 1 and day 2, then 10 mg taken once a day.

Children (6 years of age or older)

Children weighing 20 to less than 50 kg: the recommended starting dose is 2.5 mg. The maximum dose is 20 mg.

Children weighing 50 kg or more: the recommended starting dose is 5 mg. The maximum dose is 40 mg.

Overdose:

If you think you have taken too much ZESTRIL 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 (or light-headedness), drowsiness, fatigue, headache, tiredness, weakness (loss of strength)
- cough, running nose
- itching, psoriasis, sinus pain, skin rash, wheezing
- abdominal pain, diarrhea, nausea, stomach pain and indigestion, vomiting
- confusion, feeling sleepy or difficulty in going to sleep, mood changes (including signs of depression), seen and/or heard hallucinations, strange dreams
- changes in the way things smell or taste, dry mouth, numbness or tingling in the fingers or toes
- rapid heartbeat
- impotence
- hair loss
- anemia

In patients with high blood pressure, fainting is uncommon. However, fainting may become common in patients with heart failure.

In patients with coronary heart disease, an excessive drop in blood pressure may be experienced.

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

ZESTRIL 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, nurse 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	√		

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

Symptom/effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		√	
Uncommon	**Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Liver and Pancreas Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	

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

Symptom/effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Rare	**Decreased Platelets:** bruising, bleeding, fatigue and weakness		√	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
Very Rare	**Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis):** any combination of itchy skin, rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain.			√

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

HOW TO STORE IT

Keep ZESTRIL out of the reach and sight of children.

Store your tablets in a cool dry place at a temperature between 15-30 °C. Keep your tablets in the container they came in.

Do not take your tablets after the expiry date on the container.

Return any unused ZESTRIL tablets to your pharmacist.

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 leaflet provides you with the most current information at the time of printing. Please refer to www.astrazeneca.ca, to see if more up-to-date information has been posted.

This document plus the full product monograph, prepared for health professionals can be found at: www.astrazeneca.ca, or by contacting the sponsor, AstraZeneca Canada Inc., at:

Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787

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