

PART III: CONSUMER INFORMATION

Pr ZESTORETIC®

lisinopril and hydrochlorothiazide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

ZESTORETIC lowers high blood pressure.

What it does:

ZESTORETIC contains a combination of 2 drugs, lisinopril and hydrochlorothiazide:

- Lisinopril 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 ZESTORETIC regularly even if you feel fine.

When it should not be used:

Do not take ZESTORETIC if you:

- Are allergic to lisinopril, hydrochlorothiazide, or to any non-medicinal ingredient 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 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.
- Are already taking a blood pressure-lowering medicine that contains 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 pressureYou can recognize ARBs because their medicinal ingredient ends in "-SARTAN".
- 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 ZESTORETIC.
- Have certain kidney diseases or have difficulty urinating or produce no urine.
- Are pregnant or intend to become pregnant. Taking ZESTORETIC during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. ZESTORETIC passes into breast milk.

What the medicinal ingredients are:

lisinopril and hydrochlorothiazide.

What the non-medicinal ingredients are:

Calcium hydrogen phosphate dihydrate, corn starch, magnesium stearate, mannitol, pregelatinized starch. The 10/12.5 mg and 20/25 mg tablets also contain red iron oxide and yellow iron oxide.

What dosage forms it comes in:

lisinopril and hydrochlorothiazide tablets: 10/12.5 mg, 20/12.5 mg, and 20/25 mg.

WARNINGS AND PRECAUTIONS

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

BEFORE you use ZESTORETIC talk to your doctor, nurse, or pharmacist if you:

- Have experienced an allergic reaction 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 or have an allergy
- 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, gout, or asthma.
- 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 a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with ZESTORETIC is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.
- Are on a low-salt diet.
- Are on dialysis.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood).
- 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 ZESTORETIC with these types of drugs may increase your chances of having an allergic reaction (angioedema).

Hydrochlorothiazide in ZESTORETIC can cause Sudden Eye Disorders:

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

These eye disorders are related and can develop within hours to weeks of starting ZESTORETIC.

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 ZESTORETIC. 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 ZESTORETIC.

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

- Adrenocorticotrophic hormone (ACTH) may be used to treat nephrotic syndrome and in diagnostic tests.
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amantadine used to treat the flu and reduce symptoms of Parkinson’s disease.
- Amphotericin B, an antifungal drug.
- Antacids.
- Drugs used to treat cancer (such as cyclophosphamide, methotrexate, temsirolimus and everolimus).
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- 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 ZESTORETIC.
- Bile acid resins used to lower cholesterol.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), diazoxide, methyldopa and beta blockers such as atenolol, metoprolol, propranolol, calcium channel blockers such as felodipine, amlodipine, nifedipine, and angiotensin II receptor blockers such as candesartan, valsartan, losartan. When taken in combination with ZESTORETIC may cause excessively low blood pressure.
- Calcium or vitamin D supplements.
- Capsaicin, an ingredient in some creams used to relieve arthritis pain.
- Corticosteroids used to treat joint pain and swelling.
- Cyclosporine used to treat autoimmune diseases.
- Digoxin, a drug used to treat heart conditions, or other medicines to control the rhythm of your heart.
- Drugs that slow down or speed up bowel function, including atropine, biperiden, domperidone and metoclopramide.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.

- Gold (sodium aurothiomalate), used to treat autoimmune conditions such as rheumatoid arthritis and psoriatic arthritis.
- Gout medications, including allopurinol and probenecid.
- Lithium, a medicine to treat bipolar disease.
- Drugs that can cause low blood potassium levels (hypokalemia) such as:
 - Laxatives,
 - Corticosteroids (such as prednisone),
 - Salicylic acid derivatives.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Drugs that can increase blood potassium levels (hyperkalemia) such as:
 - Potassium supplements,
 - Salt substitutes.
- Rituximab used to treat cancer, transplant rejection, and some autoimmune diseases.
- Sirolimus, a drug used to prevent organ rejection after a transplant.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Tetracycline antibiotics.
- Tissue plasminogen activator (TPA) that is used to dissolve blood clots that have formed in blood vessels.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dizziness
- headache
- cough
- drowsiness, fatigue, weakness
- rash
- abdominal pain, upset stomach, decreased appetite, constipation
- muscle pain or cramps

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

ZESTORETIC 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	√		
	Decreased or 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			√

PROPER USE OF THIS MEDICATION

Take ZESTORETIC exactly as prescribed.

It is recommended to take your dose at about the same time everyday.

ZESTORETIC can be taken with or without food. If ZESTORETIC causes upset stomach, take it with food or milk.

Usual Adult Dose:

The dosage of ZESTORETIC is individualized and taken once a day.

It may be prescribed as follows:

One tablet of 10/12.5mg

Or,

One or two tablets of 20/12.5mg,

One or two tablets of 20/25mg

Overdose:

If you think you have taken too much ZESTORETIC 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.

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

Symptom/effect	Talk with your doctor, nurse of pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Kidney Disorder: decreased urination, nausea, vomiting, swelling of extremities, fatigue		√	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
Increased blood sugar: frequent urination, thirst, and hunger	√		
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Rare	Decreased Platelets: bruising, bleeding, fatigue and weakness		√
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√

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

Symptom/effect	Talk with your doctor, nurse of pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
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.		√
Unknown	Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain		√
	Anemia: fatigue, loss of energy, weakness, shortness of breath		√
	Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		√

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	
Hallucinations: sensation of seeing or hearing things		√	
Lupus-like reactions: associated with fever, malaise, joint pains, myalgias, fatigues etc. May be activated, or lupus status may worsen		√	

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

HOW TO STORE IT

- Keep in the original package at room temperature (15°C to 30°C), tightly closed and protected from light.
- When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.
- Do not transfer ZESTORETIC to other pill containers.
- **Keep out of reach and sight of children.** Never take medicine in front of small children as they will want to copy you.
- Do not keep or use ZESTORETIC after the expiry date indicated on the package. Unused medicines, which you know you will no longer need, should be carefully discarded. You may wish to seek advice from your pharmacist.
- **Remember** to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

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: 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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