

## PART III: CONSUMER INFORMATION



## enalapril and hydrochlorothiazide tablets

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

### ABOUT THIS MEDICATION

#### What the medication is used for:

VASERETIC® lowers blood pressure.

#### What it does:

VASERETIC® contains a combination of 2 drugs, enalapril and hydrochlorothiazide.

Enalapril 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 a “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 VASERETIC® regularly even if you feel fine.

#### When it should not be used:

Do not take VASERETIC® if you:

- Are allergic to enalapril and hydrochlorothiazide or any non-medicinal ingredient in the formulation.
- Are allergic to sulphonamide-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 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.
- Have difficulty urinating or produce no urine.
- Are pregnant or intend to become pregnant. Taking VASERETIC® during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. VASERETIC® 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.
- Are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take VASERETIC® for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

- Have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in VASERETIC®

#### What the medicinal ingredients are:

enalapril maleate (as enalapril sodium) and hydrochlorothiazide.

#### What the non-medicinal ingredients are:

Corn starch, lactose, magnesium stearate, pregelatinized starch, sodium bicarbonate and red ferric oxide.

#### What dosage forms it comes in:

Tablet; enalapril 10 mg/hydrochlorothiazide 25 mg.

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions – Pregnancy**

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

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

- Are allergic to any drug used to lower blood pressure or penicillin
- Have bronchial asthma.
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with VASERETIC® is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.
- Are taking anti-cancer (temsirolimus, everolimus) or anti-rejection (sirolimus) medications. Use of ACE inhibitors, such as VASERETIC®, with these drugs may increase the chance of having an allergic reaction (angioedema).
- 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.
- Have lupus or gout.
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill”) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- Are on a low-salt diet.
- Are receiving gold (sodium aurothiomalate) injections.

- Are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).
- Are less than 18 years old.
- 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.

**Risk of skin cancer:**

VASERETIC<sup>®</sup> contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking VASERETIC<sup>®</sup> for many years (more than 3) or at a high dose.

While taking VASERETIC<sup>®</sup>:

- 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 of skin to sun and avoid indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
- Talk to your doctor 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 VASERETIC<sup>®</sup> 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 VASERETIC<sup>®</sup>.

You may become sensitive to the sun while taking VASERETIC<sup>®</sup>. Exposure to sunlight should be minimized.

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 VASERETIC<sup>®</sup>.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to VASERETIC<sup>®</sup>. 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 VASERETIC<sup>®</sup>:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome.
- 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.
- Amphotericin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication.
- Diuretics or “water pills”.
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. RASILEZ), or angiotensin receptor blockers (ARBs).
- Gout medications (allopurinol, uricosurics, xanthine oxidase inhibitors).
- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs. When taken in combination with VASERETIC<sup>®</sup>, they may cause excessively low blood pressure.
- Potassium-containing medicines, potassium supplements, salt substitutes that contain potassium or other drugs that may increase serum potassium (e.g., trimethoprim-containing products), as these may lead to increased levels of potassium in the blood which can be serious. In these cases, your physician may need to adjust the dosage of VASERETIC<sup>®</sup> or monitor your blood level of potassium.
- Certain pain and arthritis medicines, including gold therapy.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine.
- mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus) therapy or a medicine containing a neprilysin inhibitor (e.g., sacubitril). Taking these drugs together with VASERETIC<sup>®</sup>, could increase the risk for an allergic reaction called angioedema.

**PROPER USE OF THIS MEDICATION**

VASERETIC<sup>®</sup> is not for initial therapy. You must first be stabilized on the individual components (enalapril and hydrochlorothiazide) of VASERETIC<sup>®</sup>. If your dosage matches the dosages in VASERETIC<sup>®</sup>, your doctor may prescribe VASERETIC<sup>®</sup> taken once a day (instead of each component as a separate pill).

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

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

**Usual Adult dose:**

The maximum daily dosage should not exceed two tablets of VASERETIC® 10 mg/25 mg.

**Overdose:**

If you think you have taken too much VASERETIC® 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
- Drowsiness, fatigue, weakness
- Cough
- Rash
- Headache
- Abdominal pain, upset stomach, decreased appetite, constipation
- Muscle pain
- Sore throat
- Impotence
- Tingling of the skin

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

VASERETIC® 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			
Symptoms/Effects	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Common</b>			
<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>Low Blood Pressure:</b> dizziness, fainting, lightheadedness may occur when you go from lying or sitting to standing up or especially following exercise, and/or when it is hot and you have lost a lot of water by sweating	√		
<b>Decreased or increased levels of potassium in the blood:</b> irregular heartbeats, muscle weakness, generally feeling unwell		√	
Chest pain		√	
Breathing problems, shortness of breath		√	
<b>Uncommon</b>			
<b>Allergic Reaction / Angioedema:</b> rash/itching, hives, swelling of the face, eyes, lips, tongue or throat, hands or feet, difficulty swallowing or breathing			√
<b>Kidney Disorder:</b> decreased urination, nausea, vomiting, swelling of extremities, fatigue		√	
<b>Liver Disorder:</b> yellowing of the skin or eyes (jaundice), dark urine, 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>Rare</b>			
<b>Decreased White Blood Cells:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms (malaise, muscle pain, rash, itching, abdominal pain, nausea, vomiting, diarrhea, jaundice, or lack of appetite)		√	
<b>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness		√	
<b>Very Rare</b>			

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

Symptoms/Effects	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Toxic Epidermal Necrolysis:</b> severe skin peeling, especially in mouth and eyes			√
<b>Unknown</b>			
<b>Eye disorders:</b> - <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		√	

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

**HOW TO STORE IT**

Store your tablets at 15°C–30°C, away from heat and direct light, and out of damp places, such as the bathroom or kitchen.

**Keep all medicines out of the reach and sight of children.**

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at [MedEffect](#);
  - By calling 1-866-234-2345 (toll-free);
  - By completing a Consumer Side Effect Reporting Form and sending it by:
    - Fax to 1-866-678-6789 (toll-free), or
    - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator  
1908C  
Ottawa, ON  
K1A 0K9
- Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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.*

**MORE INFORMATION**

**If you want more information about VASERETIC®:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the [Health Canada website](#) or Organon Canada web site [www.organon.ca](http://www.organon.ca) or by calling Organon Canada at 1-844-820-5468.
- To report an adverse event related to VASERETIC®, please contact 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

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