

PART III: CONSUMER INFORMATION

 **VASERETIC[®]**

enalapril and hydrochlorothiazide tablets

This leaflet is part III of a three-part “Product Monograph” published when VASERETIC[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VASERETIC[®]. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- reducing high blood pressure

If your physician has recommended a particular diet, for instance less salt, follow the diet carefully. This could help your medicine to control your blood pressure. Your physician may also recommend weight loss. Do follow these suggestions.

What it does:

When blood pressure is high, the workload of the heart and arteries increases so that over time, these may not function as they should. In turn, this could lead to damage of the “vital organs”: brain - heart - kidneys, and result in stroke, heart failure, heart attack, blood vessel disease or kidney disease.

VASERETIC[®] is the brandname for the combination of the substances - enalapril and hydrochlorothiazide.

Enalapril is one of a class of medicines known as angiotensin converting enzyme inhibitors (ACE). They lower blood pressure by specifically blocking a naturally occurring substance called angiotensin II. Angiotensin II normally tightens your blood vessels. Enalapril allows them to relax and therefore helps lower high blood pressure.

Hydrochlorothiazide is a thiazide diuretic, often termed a “water pill”. It helps reduce edema (the swelling caused by water retention).

This combination is available **only on prescription** from your physician.

This medicine does not cure high blood pressure, **but does help control it**. So, it is important to continue taking the tablets regularly to keep your blood pressure down. You may have to take high blood pressure medicine for life.

Keep your regular appointments with your physician, even if you feel well. High blood pressure may not be easily recognized by you, because you may not “feel any symptoms”; but your physician can measure your blood pressure very easily, and check how the medicine is controlling it.

When it should not be used:

Do not take VASERETIC[®] if you:

- are allergic to VASERETIC[®] or any of its components.
- are allergic to sulphonamide-derived drugs. If you are unsure what these are, speak with your physician or pharmacist.
- are no longer able to produce urine.
- have a history of swelling of the face, lips, tongue, throat, or sudden difficulty breathing or swallowing.
- have been diagnosed with swelling of the face, lips, tongue, throat, or sudden difficulty breathing or swallowing due to genetic factors or unknown reasons (please refer to Side Effects and What to Do About Them).

What the medicinal ingredients are:

Each tablet of VASERETIC[®] is made with enalapril maleate that appears as enalapril sodium in the tablets and hydrochlorothiazide.

What the important non-medicinal ingredients are:

Each tablet of VASERETIC[®] contains the following non-medicinal ingredients: corn starch, lactose, magnesium stearate, pregelatinized starch, sodium bicarbonate and the following colouring agent: red ferric oxide.

What dosage forms it comes in:

VASERETIC[®] tablet 10 mg/25 mg (rust).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

VASERETIC[®] should not be used during pregnancy. If you discover that you are pregnant while taking VASERETIC[®], stop the medication and please contact your physician as soon as possible.

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

This medicine may not be suitable for certain people. Tell your physician or pharmacist if you think any of the following applies to you:

- You have previously taken **any** of the following and were allergic or reacted badly to it: hydrochlorothiazide or any other diuretic or "water pill"; sulfonamides (sulfa medicine); enalapril or any other medication of the same type - Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, lisinopril, captopril, particularly if you experienced swelling of the face, eyes, lips, tongue and/or throat, hands or feet, or had sudden difficulty breathing or swallowing. These are symptoms of conditions called hereditary angioedema or idiopathic angioedema.
- **You should not take this medicine if you have been diagnosed with hereditary angioedema or idiopathic angioedema (angioedema of unknown cause).**
- Dizziness or drowsiness may occasionally occur when taking medication to lower blood pressure. Therefore, before you perform tasks which may require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to your medicine.
- You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- **You are pregnant, breast-feeding or thinking of becoming pregnant.** Taking VASERETIC[®] during pregnancy can cause injury and even death to your developing baby. This medicine should not be used during pregnancy. If you become pregnant while taking VASERETIC[®], stop the medication and report to your physician as soon as possible. It is possible that VASERETIC[®] passes into breast milk. You should not breast-feed while taking VASERETIC[®].
- You suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing). Tell your physician if you experience lightheadedness especially during the first few days of therapy. If actual fainting occurs, discontinue the drug until having consulted with your prescribing physician.
- You are undergoing dialysis.
- You have any of these conditions:
 - diabetes
 - heart or blood vessel disease
 - liver disease
 - kidney disease, or difficulty in producing urine
 - bronchial asthma
 - lupus erythematosus or a history of this condition
 - gout or history of gout
- You are receiving gold (sodium aurothiomalate) injections.
- You are taking "water pills" or potassium supplements.
- You use potassium containing salt substitutes with your food.

You should also inform your physician or pharmacist if you have recently suffered from excessive vomiting or diarrhea.

If you have to undergo any dental or other surgery, inform the dentist or the physician in charge that you are taking this medicine.

Remember - This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

Do not use outdated medicine.

This medicine is not recommended for children.

INTERACTIONS WITH THIS MEDICATION

Do not take any other medicines unless you have discussed the matter with your physician or pharmacist. Certain medications tend to increase your blood pressure, for example, non-prescription preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems, or may also react badly with VASERETIC[®].

Your physician or pharmacist also needs to know if you are taking any other medication, whether they be prescription medications or over-the-counter products. It is particularly important to inform your physician or pharmacist if you are taking:

- Diuretics or "water pills"
- Any other medicines to reduce blood pressure
- Potassium-containing medicines, potassium supplements or salt substitutes that contain potassium, 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[®] or monitor your blood level of potassium.
- Diabetes medicine and/or insulin
- Lithium (a drug used to treat a certain kind of depression)
- Certain pain and arthritis medicines, including gold therapy and non-steroidal anti-inflammatory drugs.
- Alcohol
- Corticosteroids
- Cholestyramine and colestipol resins (to treat high cholesterol)
- Probenecid (a drug used to treat gout)
- D-tubocurarine (a muscle relaxant)
- Barbiturates
- Narcotics

PROPER USE OF THIS MEDICATION

Usual dose:

- Take this medicine exactly as your physician ordered.
- The absorption of this medicine is not affected by food; so it can be taken with or without a meal.
- Try to take your medicine every day at the same time. This way it becomes easy to remember your doses.
- The splitting of VASERETIC[®] 10 mg/25 mg tablets is not advised.
- The maximum daily dosage should not exceed two tablets of VASERETIC[®] 10 mg/25 mg.

Overdose:

- In case of an overdose, contact your physician, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms. The most likely symptom would be a feeling of lightheadedness or dizziness due to a sudden or excessive drop in blood pressure.

Missed Dose:

- If you miss a dose of this medicine, take it as soon as possible. However, if no more than six hours have elapsed since the missed dose, you may take that day's dose of medication and then go back to your regular dosing schedule. **Do not take a double dose.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication, including VASERETIC®, may cause side effects. Most people do not experience any problem when taking this medicine; but if you notice any of the following, have other side effects or if the condition persists or worsens, seek medical attention.

- You may experience increased skin sensitivity to sunlight. Avoid too much sunlight and do not use a sunlamp.
- Dry cough, sore throat
- Impotence
- Tingling of the skin
- The initial dose may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as faintness or dizziness and it may help to lie down. If concerned, please consult your physician or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms/Effects		Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
		Only if severe	In all cases	
Uncommon	Abdominal pain	√		
	Allergic reactions/ Angioedema (sudden difficulty breathing or swallowing, swelling of face, eyes, lips, tongue and/or throat, hands or feet)			√
	Flu-like symptoms (fever, malaise, muscle pain, rash, itching, abdominal pain, nausea, vomiting, diarrhea, jaundice, or lack of appetite)			√
	Liver impairment such as jaundice, dark/brown urine		√	
	Loss of appetite	√		
	Kidney failure/decreased urine production	√		

This is not a complete list of side effects. For any unexpected effects while taking VASERETIC®, contact your physician 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 of children.

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

Symptoms/Effects		Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
		Only if severe	In all cases	
Common	Chest pain		√	
	Dizziness/Fainting/ Lightheadedness, especially following exercise, and/or when it is hot and you have lost a lot of water by sweating			√
	Fatigue	√		
	Headache	√		
	Low blood pressure		√	
	Lasting cough		√	
	Nausea/Vomiting/ Diarrhea	√		
	Fast heart beat	√		
	Rash/Itching		√	
	Shortness of breath		√	

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, ON 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

or Merck Canada Inc. by one of the following 2 ways:

Call toll-free telephone: 1-800-567-2594
Complete a Canada Vigilance Reporting Form and:
Fax: 1-866-496-9092 or
Mail to:
Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire–Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program or Merck do not provide medical advice.

MORE INFORMATION

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

<http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc., at:
1-800-567-2594

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