

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

VASERETIC®

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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VASERETIC®**.

Serious Warnings and Precautions

VASERETIC® should **not** be used during pregnancy. Taking it during pregnancy can cause injury or even death to your baby. If you discover that you are pregnant while taking VASERETIC®, stop the medication and contact your healthcare professional **as soon as possible**.

What is VASERETIC® used for?

VASERETIC® is used to treat adults with high blood pressure.

How does VASERETIC® work?

VASERETIC® contains two medicinal ingredients:

- **Enalapril:** It is an Angiotensin-Converting Enzyme (ACE) inhibitor. This type of drug blocks your body from making a chemical called angiotensin II. When angiotensin II enters your blood:
 - your blood vessels become narrower. When this happens, your blood has less space to move in.
 - it also triggers a hormone that makes your body hold on to water.

Having more fluid in your body, in a narrow space will cause your blood pressure to go up.

ACE inhibitors help to lower your blood pressure by:

- reducing the amount of angiotensin II in your body. This allows your blood vessels to relax and become wider. It makes it easier for your blood to flow through your blood vessels.
 - lowering the amount of water your body retains.
- **Hydrochlorothiazide:** It is a diuretic. This type of drug helps your body eliminate salt and water through your urine. Having less fluid in your body will cause your blood pressure to go down.

This medicine does not cure high blood pressure but it helps control this condition.

What are the ingredients in VASERETIC®?

Medicinal ingredients: Enalapril maleate that appears as enalapril sodium in the tablets, and hydrochlorothiazide.

Non-medicinal ingredients: Corn starch, lactose, magnesium stearate, pregelatinized starch, red ferric oxide and sodium bicarbonate.

VASERETIC® comes in the following dosage forms:

Tablet: 10 mg of enalapril maleate, that appears as 8 mg of enalapril sodium in the tablets, and 25 mg of hydrochlorothiazide.

Do not use VASERETIC® if:

- You are allergic to enalapril, hydrochlorothiazide or to any of the other ingredients in VASERETIC®. VASERETIC® contains lactose.
- You have had an allergic reaction (angioedema):
 - to any other ACE inhibitor. You can tell you are taking or have taken an ACE inhibitor because these types of medicines have ingredients that end with “-PRIL”
 - have been diagnosed with hereditary angioedema. This is an increased risk of getting an allergic reaction that is passed down through your family
 - where the reason for it is not known. This is called idiopathic angioedema.

Signs of an allergic reaction include:

- swelling of the hands, feet, ankles, face, lips, tongue and throat
- suddenly having trouble breathing or swallowing

Make sure that you tell your healthcare professional that this has happened to you before.

- You have diabetes or kidney disease and are already taking a blood pressure-lowering medicine that contains aliskiren.
- You 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.
- You have difficulty urinating or produce no urine.
- You are allergic to sulphonamide-derived medicines (sulfa drugs). Most of them have a medicinal ingredient that ends in “-MIDE”.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VASERETIC®. Talk about any health conditions or problems you may have, including if you:

- previously had airway surgery (e.g., in your nose, throat, trachea or lungs)
- have a history of allergic reactions (angioedema). You should be aware that black patients have a higher risk of experiencing these types of reactions while taking ACE inhibitors
- are undergoing dialysis
- have recently or are planning to have allergy shots for bee or wasp stings
- are undergoing low-density lipoprotein (LDL)-apheresis, a treatment that removes cholesterol from your blood
- have recently suffered from excessive vomiting or severe diarrhea
- have heart or blood vessel disease
- have narrowing of an artery or a heart valve
- have liver disease
- have low blood pressure
- have a history of allergies
- have a history of bronchial asthma
- have lupus or gout
- have a greater chance of developing skin cancer because you:
 - had skin cancer or have a family history of skin cancer
 - have light coloured skin
 - get sunburned easily, or
 - are taking medicines to suppress your immune system
- are planning to have dental or any other type of surgery and will be given anesthesia. Tell your healthcare professional that you are taking this medicine
- are taking anti-cancer or anti-rejection medicines such as temsirolimus, everolimus and sirolimus
- are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril)
- are taking dipeptidyl peptidase IV (DPP-IV) inhibitors. You can recognize a DPP-IV inhibitor because its medicinal ingredient ends in “-GLIPTIN”
- are taking other blood pressure-lowering medicines
- are on a low-salt diet
- are taking an angiotensin receptor blockers (ARBs). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”
- are taking a medicine that contains aliskiren
- are receiving gold (in the form of sodium aurothiomalate) injections
- are allergic to penicillin or sulphonamide-derived medicines
- are at risk for developing high levels of potassium in your blood. This can be serious and can happen if you:
 - are taking:
 - a salt substitute that contains potassium
 - potassium supplements

- potassium-sparing diuretic (a specific kind of “water pill” that makes your body hold onto potassium such as spironolactone, eplerenone, triamterene or amiloride)
- other medications that may increase potassium in your blood (e.g., trimethoprim-containing products)
- have diabetes or any kidney problems

Other warnings you should know about:

- **Breastfeeding:** VASERETIC® passes into breastmilk and could harm a breastfed baby. VASERETIC® is **not** recommended during breastfeeding. Talk to your healthcare professional about ways to feed your baby if you are planning to breastfeed while taking VASERETIC®.
- **Driving and using machines:** VASERETIC® may impair your ability to drive or to use machines. Wait until you know how VASERETIC® affects you before driving or using machines. Do not drive or use machines if VASERETIC® impairs your ability to do so safely.
- **Laboratory tests and monitoring:** Your healthcare professional may do blood tests before you take VASERETIC® and/or during treatment. These tests will check:
 - The amount of blood cells in your body.
 - That your thyroid gland, liver and kidneys are working properly.
 - The levels of electrolytes in your blood.
 - The levels of cholesterol and triglycerides (types of fat) in your blood

VASERETIC® can cause serious side effects, including:

- **Allergic reaction / Angioedema:** Some patients have reported experiencing allergic reactions (angioedema) while taking VASERETIC®. This may happen at any time during treatment with VASERETIC® and can be life threatening. Very rarely, cases have resulted in death. If you experience an allergic reaction, **stop** taking VASERETIC® and tell your healthcare professional **right away**.
- **Blood disorders:** ACE inhibitors, such as the enalapril component of VASERETIC®, may cause:
 - **Bone marrow depression** (a large decrease in the production of blood cells and platelets by the bone marrow)
 - **Neutropenia / Agranulocytosis** (decrease in white blood cells)
- **Breathing Problems:** The hydrochlorothiazide component of VASERETIC may cause severe shortness of breath or difficulty breathing after taking VASERETIC. Stop taking VASERETIC and get immediate medical help.
- **Cough:** You may develop a dry and persistent cough while taking VASERETIC®. This usually goes away once you stop taking VASERETIC® or when the dose is lowered. Tell your healthcare professional if you experience this symptom.
- **Eyes:** The hydrochlorothiazide component of VASERETIC® may cause:

- **Choroidal effusion** (abnormal accumulation of fluid in your eyes)
 - **Glaucoma** (increased pressure in your eyes). This may lead to permanent vision loss if left untreated.
 - **Myopia** (near sightedness)
- These eye disorders can develop within hours to weeks of starting VASERETIC®. If you experience eye problems, **stop** taking VASERETIC® and tell your healthcare professional **right away**.
- **Hypotension** (low blood pressure): You may feel dizzy or light-headed:
 - Particularly in the first few days after you start taking VASERETIC® or when your dose is increased.
 - When you exercise or when the weather is hot.

You should lie down if this happens. If you faint, talk to your healthcare professional **as soon as possible**. Before doing any tasks that require special attention, wait until you know how you respond to VASERETIC®.

- **Kidney disorders:** The hydrochlorothiazide component of VASERETIC® may cause or worsen kidney problems. This includes kidney damage and/or decreased production of urine. If you experience signs of kidney problems, tell your healthcare professional **right away**.
- **Skin:** Treatment with hydrochlorothiazide, a component of VASERETIC®, may increase your risk of developing non-melanoma skin cancer. The risk is higher if you have been taking VASERETIC® for many years (more than 3) or at a high dose.

While taking VASERETIC®:

- Regularly check your skin for any new lesions such as patches of pigmented skin, lumps, bumps, sores or moles. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- You may become sensitive to the sun.
- Limit your exposure to sun and avoid indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.

Talk to your healthcare professional **right away** if you become more sensitive to the sun or UV light or if you develop any new skin lesions while taking VASERETIC®.

See the Serious side effects and what to do about them table, below, for more information on these and other serious side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VASERETIC®:

- Medicines that can increase the levels of potassium in your blood. These include:
 - potassium-sparing medicines (such as spironolactone, eplerenone, triamterene or amiloride)

- potassium supplements
 - salt substitutes that contain potassium
 - other medicines that may increase serum potassium (e.g., trimethoprim-containing medicines)
- Medicines used to treat diabetes. These include:
 - DPP-IV inhibitors, such as alogliptin, linagliptin, saxagliptin and sitagliptin
 - insulin
 - other oral antidiabetic medicines
- Medicines that lower your blood pressure. These include:
 - guanethidine
 - methyldopa
 - beta blockers
 - vasodilators
 - calcium channel blockers
 - Angiotensin-Converting Enzyme (ACE) inhibitors
 - Angiotensin Receptor Blockers (ARBs)
 - aliskiren-containing medicines
 - diuretics (“water pills”)
- Alcohol
- Lithium - used to treat bipolar disorder
- Barbiturates – used to treat anxiety, insomnia and seizures
- Carbamazepine, topiramate – used to prevent and control seizures
- Narcotics – used to relieve pain
- Amphotericin B – used to treat fungal infections
- Adrenocorticotrophic hormone (ACTH) – used to treat West Syndrome
- Corticosteroids – used to treat joint pain and swelling and other conditions
- Digoxin – used to treat heart conditions
- Calcium and vitamin D supplements
- Gout medicines, including allopurinol, uricosurics, xanthine oxidase inhibitors and probenecid
- Anticancer medicines, including cyclophosphamide and methotrexate – used to treat cancer
- Gold (in the form of sodium aurothiomalate) injections – used to treat arthritis
- Temsirolimus, everolimus, sirolimus – used to treat certain cancers and/or used to prevent rejection of organ transplants
- Bile acid resins, such as cholestyramine and cholestipol resins – used to lower cholesterol
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as naproxen, ibuprofen and celecoxib – used to treat pain and swelling
- Medicines that slow down or speed up bowel functions, such as atropine, metoclopramide, and domperidone

- Medicines containing a neprilysin inhibitor (e.g., sacubitril)
- Pressor amines, such as norepinephrine
- Antidepressants, in particular Selective Serotonin Reuptake Inhibitors (SSRIs), such as citalopram, escitalopram and sertraline
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare

How to take VASERETIC®:

- Swallow the tablet whole. You should not split or break VASERETIC® tablets.
- Take VASERETIC®:
 - exactly as your healthcare professional tells you
 - at the same time every day
 - with or without food. If VASERETIC® upsets your stomach, take it with food or milk.

Usual dose:

Take VASERETIC® as directed by your healthcare professional.

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

Overdose:

If you think you, or a person you are caring for, have taken too much VASERETIC®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Symptoms of an overdose include:

- Light-headedness and dizziness. This is due to a sudden or extreme drop in blood pressure.
- Feeling weak, feeling sleepy, irregular heartbeat, muscle pain or cramps. These are signs of an electrolyte imbalance.
- Dehydration. This is due to an increase or extreme production of urine.

Missed dose:

If you have forgotten to take your dose during the day, take the next dose at the usual time. Do not double dose.

What are possible side effects from using VASERETIC®?

These are not all the possible side effects you may have when taking VASERETIC®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Fever

- Feeling weak or tired
- Skin rash
- Feeling sick
- Vomiting
- Abdominal pain
- Muscle cramps
- Bladder infection
- Headache
- Dizziness
- Tingling of the skin
- Dry cough
- Impotence (not able to have an erection)
- Difficulty swallowing
- Indigestion
- Constipation
- Passing Gas, gas
- Dry mouth
- Ringing in the ears
- Gout (Intense joint pain, pain after the intense pain is no longer there, inflammation and redness of the affected joint, limited movement of the affected joint).
- Back pain
- Joint pain, joint stiffness
- Difficulty sleeping
- Nervousness
- Sleepiness
- Vertigo (you have a spinning or moving sensation)
- Itching
- Excessive sweating
- Changes in taste
- Decreased libido
- Eating disorder (anorexia)
- Abnormal dreams
- Confusion
- Hair loss
- Flushed skin
- Sensitivity to light
- Loss of smell
- Pink eye

- Dry eyes
- Watery eyes
- Loss of hearing
- Breast growth in males

VASERETIC® can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Breathing problems, shortness of breath		√	
Chest pain		√	
Decreased or increased levels of potassium in the blood: irregular heartbeats, muscle weakness, generally feeling unwell		√	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up, following exercise and/or when it is hot and you have lost a lot of water by sweating)	√		
Non-melanoma skin cancer: 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.		√	
Tachycardia (abnormally fast heartbeat)	√		
UNCOMMON			
Allergic Reaction / Angioedema: difficulty swallowing or breathing; swollen face, hands and feet, genitals, tongue, throat; wheezing; hives or rash; swelling			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
of the digestive tract causing diarrhea, nausea or vomiting			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness		√	
Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Hyperglycemia: (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	√		
Kidney Disorder: decreased urination, nausea, vomiting, swelling of extremities, fatigue		√	
Liver Disorder: yellowing of the skin or eyes (jaundice), dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat.			√
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			√
Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			
RARE			
Bone marrow depression (a large decrease in the production of blood cells and platelets by the bone marrow): bleeding, bruising, chills, fatigue, fever, infections, weakness, shortness of breath or other signs of infection		√	
Neutropenia/Agranulocytosis (decrease in white blood cells): frequent infection, fatigue, fever, aches, pains and flu-like symptoms		√	
Pulmonary edema (excess fluid in the lungs): difficulty breathing that worsens with activity or when lying down, extreme shortness of breath, wheezing or gasping for breath, cold clammy skin, irregular heartbeat, cough that produces frothy sputum, blue-tinged lips			√
Raynaud's phenomenon (episodes of reduced blood flow): cold feeling in fingers and toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue			√
VERY RARE			
Acute Respiratory Distress Syndrome (ARDS): Severe difficulty breathing, including shortness of breath. fever, weakness, or confusion.			√
Stevens-Johnson syndrome (SJS) / Toxic Epidermal Necrolysis			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
(TEN) / pemphigus (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, can be accompanied with fever, chills, headache, cough, body aches or swollen glands			
SIADH—syndrome of inappropriate antidiuretic hormone secretion: concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits (seizures) which may be due to inappropriate secretion of ADH (antidiuretic hormone).			√
UNKNOWN			
Ataxia (lack of muscle coordination): difficulty with fine motor tasks such as eating, writing or buttoning shirt; difficulty walking; loss of balance; slurring speech		√	
Eye Disorders: Choroidal effusion (abnormal accumulation of fluid in your eyes): changes in your vision, can be accompanied with eye pain. Glaucoma: increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, and changes in vision (Hazy or blurred vision, sudden sight loss). Myopia (near sightedness): blurred vision, difficulty focusing on objects far away, need to squint, headache caused by eyestrain, fatigue.			√
Herpes Zoster virus (shingles): a painful skin rash of fluid-filled	√		

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
blisters, blisters appear along a strip of skin, itching			
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

- Store your tablets between 15°C - 30°C.
- Protect from moisture.
- Keep out of reach and sight of children.

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 Patient Medication Information by visiting the Health Canada website: (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp> the manufacturer's website www.organon.ca , or by calling [1-844-820-5468](tel:1-844-820-5468).

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