

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **VASOTEC®** enalapril tablets

Read this carefully before you start taking VASOTEC® 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 **VASOTEC®**.

#### **Serious Warnings and Precautions**

VASOTEC® 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 VASOTEC®, stop the medication and contact your healthcare professional **as soon as possible**.

#### **What is VASOTEC® used for?**

VASOTEC® is used to treat:

- children (less than 16 years of age) and adults with high blood pressure
- adults with heart failure

It can be used alone or along with other medications to treat your condition.

#### **How does VASOTEC® work?**

VASOTEC® belongs to a group of medicines called Angiotensin-Converting Enzyme (ACE) inhibitors. These types of medicines block 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.

The lowering of your blood pressure makes it easier for your heart to pump blood. It can also help your heart work better if you have heart failure.

This medicine does not cure high blood pressure or congestive heart failure but it helps control these conditions.

### **What are the ingredients in VASOTEC®?**

Medicinal ingredient: Enalapril maleate that appears as enalapril sodium in the tablets.

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

VASOTEC® 10 mg and 20 mg tablets also contain red iron oxide.

VASOTEC® 20 mg tablets also contain yellow iron oxide.

### **VASOTEC® comes in the following dosage forms:**

Tablets: 5 mg, 10 mg and 20 mg of enalapril maleate that appears as 4 mg, 8 mg and 16 mg of enalapril sodium in the tablets respectively.

VASOTEC® 2.5 mg tablet is no longer available, but this strength, as enalapril maleate 2.5 mg tablets, is available at the pharmacy.

### **Do not use VASOTEC® if:**

- You are allergic to enalapril or to any of the other ingredients in VASOTEC®
- 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 VASOTEC® for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VASOTEC®. 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 received 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
  - 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. Use of ACE inhibitors, such as VASOTEC®, with these drugs may increase the chance of having an allergic reaction (angioedema).
  - 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 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:**

**VASOTEC® can cause serious side effects, including:**

- **Allergic reaction / Angioedema:** Some patients have reported experiencing allergic reactions (angioedema) while taking VASOTEC®. This may happen at any time during treatment with VASOTEC® and can be life threatening. Very rarely, cases have resulted in death. If you experience an allergic reaction, **stop** taking VASOTEC® 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 VASOTEC® 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, **stop** taking VASOTEC® and talk to your healthcare professional. Before doing any tasks that require special attention, wait until you know how you respond to VASOTEC®.

- **Blood disorders:** ACE inhibitors, such as VASOTEC®, may cause:
  - **Neutropenia / Agranulocytosis** (decrease in white blood cells)
  - **Bone marrow depression** (a large decrease in the production of blood cells and platelets by the bone marrow)
- **Hypoglycemia** (low blood sugar): VASOTEC® may cause low blood sugar in patients with
  - Diabetes who are taking oral antidiabetic medicines or insulin.
  - Kidney problems

You should closely monitor your blood sugar level, especially during the first month of your treatment with VASOTEC®.

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

**Cough:** You may develop a dry and persistent cough while taking VASOTEC®. This usually goes away once you stop taking VASOTEC® or when the dose is lowered. Tell your healthcare professional if you experience this symptom.

**Breastfeeding:** VASOTEC® passes into breastmilk and could harm a breastfed baby. VASOTEC® is **not** recommended during breastfeeding. Talk to your healthcare professional about ways to feed your baby if you are planning to breastfeed while taking VASOTEC®.

**Laboratory tests and monitoring:** Your healthcare professional may do blood tests before you take VASOTEC® and/or during treatment. These tests will check:

- The level of white blood cells in your body.
- That your liver or kidneys are working properly.
- The potassium levels in your blood.

**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 VASOTEC®:**

- Medicines that lower your blood pressure. These include:
  - Angiotensin-Converting Enzyme (ACE) inhibitors
  - diuretics (“water pills”)
  - aliskiren-containing medicines
  - Angiotensin Receptor Blockers (ARBs)
  - beta blockers
- 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 aligliptin, linagliptin, saxagliptin and sitagliptin
  - Insulin
  - Other oral antidiabetic medicines
- Gold (in the form of sodium aurothiomalate) injections – used to treat arthritis

- Lithium - used to treat bipolar disorder
- Temsirolimus, everolimus, sirolimus – used to treat certain cancers and/or used to prevent rejection of organ transplants
- Medicines containing a neprilysin inhibitor (e.g., sacubitril)
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as naproxen, ibuprofen and celecoxib – used to treat pain and swelling
- Certain medicines that you can buy without a prescription are known to cause your blood pressure to go up. These include medicines:
  - to control your hunger
  - for asthma
  - to treat colds and coughs
  - to treat allergies (such as hayfever)
  - to treat sinus problems

#### How to take VASOTEC®:

- Keep your regular appointments with your health care professional, even if you feel well. You may not easily recognize signs of high blood pressure. Your healthcare professional will measure your blood pressure and check how the medicine is controlling it.
- If your healthcare professional has given you specific instructions to follow, for example to eat a low-salt diet or to lose weight, you should follow them.
- Swallow the tablet **whole**. **You should not split or break VASOTEC® tablets.**
- Take VASOTEC®
  - exactly as your healthcare professional tells you
  - with or without food
  - at about the same time every day

#### Usual dose:

Your healthcare professional will decide the best dose for you based on your needs.

#### Overdose:

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

Symptoms of an overdose include feeling light-headed or dizzy. This can happen because of a sudden or extreme drop in blood pressure.

**Missed dose:**

- If it has been **less** than 6 hours since you missed taking it, take your dose as soon as possible and then go back to your regular schedule.
- If it has been **more** than 6 hours since you missed taking it, skip the missed dose. Take the next dose at your usual time.

Do not take two doses at the same time.

**What are possible side effects from using VASOTEC®?**

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

Side effects include:

- Headache
- Feeling weak or tired
- Dry Cough
- Sore throat
- Runny nose
- Abdominal pain
- Muscle pain
- Joint pain
- Difficulty sleeping
- Sleepiness
- Nervousness
- Decreased urination
- Impotence (not able to have an erection)
- Bladder infection
- Difficulty swallowing
- Eating disorder (anorexia)
- Indigestion
- Nausea
- Vomiting
- Bloating
- Cramps
- Constipation
- Tongue changing colour
- Dry mouth
- Mouth sores
- Changes in taste

- Abnormal dreams
- Confusion
- Hair loss
- Flushed skin
- Sensitivity to light
- Tingling of the skin
- Excessive sweating
- Loss of smell
- Ringing in the ears
- Hearing loss
- Blurred vision
- Pink eye
- Dry eyes
- Watery eyes
- Breast growth in males

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	
<b>COMMON</b>			
Diarrhea	√		
<b>Electrolyte imbalance:</b> feeling weak or tired, muscle pain or cramps, irregular heartbeat	√		
<b>Hypotension</b> (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)			√
Rash/Itching		√	
<b>UNCOMMON</b>			
<b>Allergic reactions / Angioedema:</b> difficulty swallowing or breathing;			√



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	
swollen face, hands and feet, genitals, tongue, throat; wheezing; hives or rash; swelling of the digestive tract causing diarrhea, nausea or vomiting			
<b>Hypoglycemia</b> (low blood sugar): thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling trembling, nervousness, sweating, low energy	√		
<b>Kidney disorder:</b> change in frequency of urination, nausea, vomiting, swelling of the hands and feet, fatigue			√
<b>Liver disorder:</b> yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		√	
Loss of appetite	√		
<b>Myocardial infarction</b> (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.			√
<b>Stroke</b> (bleeding or blood clot in			√

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	
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 swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			
<b>Rare</b>			
<b>Bone marrow depression</b> (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			√
<b>Neutropenia / Agranulocytosis</b> (decrease in white blood cells): frequent infection, fatigue, fever, aches, pains and flu-like symptoms		√	
<b>Stevens-Johnson syndrome (SJS) / Toxic Epidermal Necrolysis (TEN) / pemphigus</b> (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			√

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.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
- Keep container tightly closed, away from heat and direct light
- Protect from moisture
- Discard remaining tablets six months after opening the bottle
- Keep out of reach and sight of children

### If you want more information about VASOTEC®:

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.organon.ca](http://www.organon.ca), or by calling 1-844-820-5468.

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