

## PATIENT MEDICATION INFORMATION

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

Pr **VIACORAM**<sup>®</sup>

#### **Perindopril arginine and amlodipine (as amlodipine besylate) tablets**

Read this carefully before you start taking **VIACORAM** 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 **VIACORAM**.

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

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

#### **What is VIACORAM used for?**

VIACORAM is used in adults, aged 18 to 65, to treat mild to moderate **high blood pressure**.

#### **How does VIACORAM work?**

VIACORAM contains 2 medicines, perindopril arginine and amlodipine. They work together to control your blood pressure.

- Perindopril arginine belong to a class of medicines called angiotensin converting enzyme (ACE) inhibitors. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'. It works by relaxing the blood vessels so blood can flow more easily.
- Amlodipine is a calcium channel blocker. It also works by relaxing the blood vessels.

This medicine does not cure your high blood pressure. It helps to control it. Therefore, it is important to continue taking VIACORAM regularly even if you feel fine. Do not stop taking your medicine without talking to your healthcare professional.

#### **What are the ingredients in VIACORAM?**

Medicinal ingredients: perindopril arginine and amlodipine (as amlodipine besylate)

Non-medicinal ingredients: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose

#### **VIACORAM comes in the following dosage forms:**

tablets: 3.5 mg /2.5 mg, 7 mg / 5 mg, 14 mg / 10 mg.

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**Do not use VIACORAM if you:**

- are allergic to:
  - perindopril
  - amlodipine
  - other ACE inhibitors
  - medicines of the dihydropyridine type (a type of calcium channel blocker, also used to lower blood pressure)
  - any non-medicinal ingredient in VIACORAM (see **What are the ingredients in VIACORAM?**)
- have had an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing:
  - to any other ACE inhibitor
  - where the reason is not known (idiopathic angioedema)
- have been diagnosed with hereditary angioedema (an increased risk of getting an allergic reaction that is passed down in families)
- are taking a medicine for heart failure containing sacubitril/valsartan. Taking VIACORAM with sacubitril/valsartan increases the risk of serious allergic reaction (angioedema). You must wait at least 36 hours after your last dose of sacubitril/valsartan before starting VIACORAM.
- have kidney problems, such as:
  - a narrowing of the blood vessels to one or both kidneys (renal artery stenosis)
  - you are on dialysis or receive any other type of blood filtration. Depending on the machine that is used, VIACORAM may not be suitable for you.
- are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease
- have heart problems, such as:
  - aortic stenosis, a narrowing of the aortic heart valve
  - problems with the heart muscle (hypertrophic cardiomyopathy)
  - heart failure
- are pregnant or planning to become pregnant. Taking VIACORAM during pregnancy can cause injury and even death to your baby.
- are breastfeeding. VIACORAM passes into breast milk.
- are lactose intolerant or have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in VIACORAM.

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

- are allergic to any drug used to lower blood pressure
  - are of African origin
  - have a severe increase in blood pressure (hypertensive crisis)
  - have low blood pressure
  - are taking any of the following medicines:
    - other blood pressure lowering medicines, such as:
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- aliskiren
  - an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".
  - other ACE inhibitors
- anti-cancer or medicines used to prevent organ rejection after a transplant such as temsirolimus, everolimus, sirolimus, cyclosporine
- non-steroidal anti-inflammatory drugs, used to treat pain and inflammation
- medicines used to manage diabetes (dipeptidyl peptidase IV (DPP-IV) inhibitors). You can recognize a DPP-IV inhibitor because its medicinal ingredient ends in "-GLIPTIN".
- medicines containing a neutral endopeptidase inhibitor (e.g., sacubitril) to treat heart failure
- allopurinol, used to treat gout
- procainamide, used to treat irregular heartbeat
- have diabetes, heart, liver or kidney problems (including kidney transplantation)
- are on dialysis
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating
- are at risk for developing high levels of potassium in your blood (hyperkalemia). This can be serious and can happen if you are taking:
  - a salt substitute that contains potassium
  - potassium supplements
  - a kind of "water pill" (potassium sparing) that makes your body hold on to potassium
  - other medicines that may increase potassium in your blood, such as the blood thinner heparin or trimethoprim or sulfamethoxazole, antibiotics used to treat bacterial infections
- are on a low-salt diet
- have systemic lupus erythematosus (SLE), an autoimmune disease that can affect many parts of the body
- have a skin condition known as scleroderma or "hard skin" (thickening of the skin)
- have recently received or are planning to get allergy shots for bee or wasp stings
- have a condition in which your body releases too much of the hormone aldosterone in your blood (primary aldosteronism)
- are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood)
- are receiving gold (sodium aurothiomalate) injections

**Other warnings you should know about:**

VIACORAM can cause serious side effects, including:

- **Allergic reaction / Angioedema:** Allergic reactions (angioedema) causing swelling of tissues under the skin, sometimes affecting the face and throat, have happened in people taking VIACORAM. These allergic reactions may happen at any time during treatment with VIACORAM and can be life threatening. Very rarely, cases have been fatal. If you experience an allergic reaction, stop taking VIACORAM and get immediate medical help.
  - **Hypotension (low blood pressure):** You may feel dizzy or light-headed:
    - in the first few days after you start taking VIACORAM
    - when your dose is increased
    - when you exercise
    - when the weather is hot
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You should lie down if this happens. If you faint, stop taking VIACORAM and talk to your healthcare professional.

- **Blood disorders:** ACE inhibitors, such as VIACORAM, may cause:
  - neutropenia / agranulocytosis (decrease in white blood cells)
  - thrombocytopenia (low blood platelets)
  - anaemia (low red blood cells)
- **Hypoglycemia (low blood sugar):** VIACORAM 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 VIACORAM.

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

**Increased sensitivity of the skin to sun:** Your skin may become sensitive to the sun while you are taking VIACORAM. Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside. Talk to your healthcare professional if your skin gets itchy and red after being exposed to sunlight.

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

**Blood tests:** Your healthcare professional may do blood tests before you take VIACORAM and/or during treatment. These tests may check:

- the level of red and white blood cells and platelets in your body
- that your liver or kidneys are working properly
- the potassium levels in your blood

**Surgery:** Before surgery or general anesthesia (even at the dentist's office), tell your healthcare professional that you are taking VIACORAM. You may experience a sudden fall in blood pressure when you are under general anesthesia.

**Driving and using machines:** Before you perform tasks, which may require special attention, wait until you know how you respond to VIACORAM. Dizziness, headache, fatigue, nausea, weariness or fainting can occur, especially after the first dose and when the dose is increased.

**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 VIACORAM.**

- medicines that lower your blood pressure. These include:
    - diuretics ("water pills")
    - aliskiren-containing medicines
    - angiotensin receptor blockers (ARBs)
    - other ACE inhibitors
    - calcium channel blockers
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- medicines that can increase the levels of potassium in your blood. These include:
    - salt substitutes that contains potassium
    - potassium supplements
    - potassium-sparing medicines, such as spironolactone, eplerenone, triamterene, amiloride
    - heparin, used to thin the blood and prevent blood clots
    - medicines affecting the immune system, such as cyclosporine, tacrolimus
    - other medicines that may increase serum potassium, such as the antibiotics trimethoprim and sulfamethoxazole
  - medicines used to treat diabetes. These include:
    - insulin
    - metformin and other oral medicines
    - a class of medicine called DPP-IV inhibitors such as sitagliptin, linagliptin, saxagliptin
  - allopurinol, used to treat gout
  - dextran sulphate, used to treat life-threatening low blood pressure
  - lithium used to treat bipolar disorder
  - a class of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling, such as ASA, ibuprofen, naproxen, celecoxib
  - a class of medicines called vasodilators, including nitrates, such as nitroglycerin, used to treat chest pain
  - procainamide used to treat irregular heartbeats
  - medicines to treat mental health problems such as depression, anxiety and schizophrenia, such as tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics
  - medicines that suppress the immune system, such as ciclosporin, tacrolimus
  - medicines used to treat low blood pressure, shock and asthma, such as ephedrine, noradrenaline, adrenaline
  - baclofen, used to treat muscle stiffness in diseases such as multiple sclerosis
  - antibiotics, used to treat bacterial infections, such as rifampicin, erythromycin, clarithromycin
  - medicines used to treat epilepsy, such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone
  - medicines used to treat fungal infections, such as itraconazole, ketoconazole
  - alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin
  - corticosteroids used to treat inflammation
  - gold salts, especially when given intravenously, used to treat rheumatoid arthritis
  - medicines used to treat HIV/AIDS, such as ritonavir, indinavir, nelfinavir
  - estramustine, used to treat prostate cancer
  - St John's wort, an herbal medicine used to treat depression
  - simvastatin, used to lower cholesterol
  - treatment for bee and wasp allergies
  - tetracosactide, used as a diagnostic agent
  - medicines containing neutral endopeptidase (NEP) inhibitors, such as sacubitril, available in combination with valsartan, used to treat heart failure
  - a class of medicines called mTOR inhibitors, used to prevent organ rejection, such as sirolimus, everolimus, temsirolimus
  - grapefruit or grapefruit juice
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**How to take VIACORAM:**

- Take VIACORAM:
  - exactly as prescribed
  - at the same time each day, preferably **in the morning**, before a meal
  - swallowed whole, with water

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you based on your needs.

**Overdose:**

Excess fluid may accumulate in your lungs (this is called a pulmonary oedema), causing shortness of breath. This may develop up to 24-48 hours after taking VIACORAM.

If you think you, or a person you are caring for, have taken too much VIACORAM, contact a healthcare professional, 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, take the next one at the usual time. Do not double dose.

**What are possible side effects from using VIACORAM?**

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

Side effects may include:

- cough (often described as dry and irritating, usually is worse at night or when lying down)
  - headache
  - stomach pain
  - diarrhea, nausea
  - changes in bowel habits
  - change in weight (increase or decrease)
  - dry mouth, abnormal taste
  - dizziness, vertigo (feeling of spinning)
  - tiredness, fatigue, drowsiness
  - trouble sleeping
  - rash, itching
  - increased sweating
  - flushing
  - tingling of the skin, pins and needles sensation
  - back pain, muscle pain, joint pain
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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>VERY COMMON</b>			
<b>Edema</b> (swelling of the hands, ankles or feet caused by too much fluid building up inside the body): swollen or puffy legs or hands, feeling heavy, achy or stiff	✓		
<b>COMMON</b>			
<b>Hyperkalemia</b> (too much potassium in the blood): irregular heartbeat, muscle weakness and generally feeling unwell		✓	
<b>Persistent Cough</b>		✓	
<b>UNCOMMON</b>			
<b>Angioedema and Severe Allergic Reaction:</b> rash, hives, swelling of the face, hands and feet, genitals, lips, tongue or throat, difficulty swallowing or breathing, wheezing, swelling of the digestive tract causing stomach pain, diarrhea, nausea or vomiting			✓
<b>Blood Disorders:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms, bruising, bleeding, weakness, small purple or red dots under the skin		✓	
<b>Bronchospasm:</b> difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing			✓
<b>Chest pain</b>		✓	
<b>Cerebrovascular accident/Stroke</b> (bleeding or blot clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurred vision, difficulty swallowing or speaking, lethargy, dizziness, fainting, vomiting, trouble understanding, trouble with walking and loss of balance			✓

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>Depression</b> (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide		✓	
<b>Electrolyte Imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
<b>Erectile Dysfunction:</b> unable to get or keep an erection	✓		
<b>Hyperglycemia</b> (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision, fatigue	✓		
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	✓		
<b>Kidney Problems:</b> change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
<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>Palpitations</b> (fast beating, fluttering or pounding heart):		✓	

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	
skipping beats, beating too fast, pounding, fluttering rapidly			
<b>Pemphigoid/Pemphigus:</b> blisters of different sizes develop on the skin			✓
<b>RARE</b>			
<b>Acute Renal Failure</b> (severe kidney problems): confusion, itchiness or rashes, puffiness in your face and hands, swelling in your feet or ankles, urinating less or not at all, weight gain			✓
<b>SIADH</b> (syndrome of inappropriate antidiuretic hormone secretion): dark urine, nausea, vomiting, muscle cramps, confusion and fits (seizures)		✓	
<b>Worsening of Psoriasis</b> (chronic skin disease): red, itchy, scaly patches of the skin		✓	
<b>VERY RARE</b>			
<b>Liver Problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
<b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea and vomiting, tenderness when touching the abdomen			✓
<b>Steven-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)</b> (severe skin reactions): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine			✓
<b>UNKNOWN</b>			

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>Extrapyramidal Disorder:</b> muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want, tremors, involuntary facial movements			✓
<b>Raynaud's Phenomenon</b> (episodes of reduced blood flow): cold feeling in fingers or toes (and sometimes nose, lips and ears), prickly or stinging feeling, change in skin colour to white then blue		✓	

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:

- Keep out of reach and sight of children.
- Store at room temperature (15-30°C). Protect from light.
- Do not use after the expiry date stated on the carton, blister or bottle.

#### If you want more information about VIACORAM:

- 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.servier.ca](http://www.servier.ca)), or by calling 1-800-363-6093.

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