

# Patient Medication Information

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

Pr **VIACORAM**®

### perindopril arginine and amlodipine tablets

This Patient Medication Information is written for the person who will be taking **VIACORAM**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **VIACORAM**, talk to a healthcare professional.

### Serious warnings and precautions box

- 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 VIACORAM is used for:

VIACORAM is used in adults (18 to 65 years of age) to treat mild to moderate high blood pressure.

### How VIACORAM works:

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

- Perindopril arginine belongs to a class of medicines called angiotensin-converting enzyme (ACE) inhibitors. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'.
- Amlodipine is a calcium channel blocker.

Both work by relaxing your blood vessels so blood can flow more easily. This helps to lower your blood pressure.

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.

### The ingredients in VIACORAM are:

Medicinal ingredients: perindopril arginine and amlodipine besylate

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

**VIACORAM comes in the following dosage form:**

Tablets: 3.5 mg / 2.5 mg, 7 mg / 5 mg, and 14 mg / 10 mg of perindopril arginine / amlodipine (as amlodipine besylate).

**Do not use VIACORAM if:**

- you are allergic to:
  - perindopril;
  - amlodipine;
  - any of the other ingredients in VIACORAM;
  - other ACE inhibitors (used to lower blood pressure);
  - medicines of the dihydropyridine type (a type of calcium channel blocker, also used to lower blood pressure).
- you ever had an allergic reaction (angioedema) involving 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).
- you have been diagnosed with hereditary angioedema (an increased risk of getting an allergic reaction that is passed down in families).
- you 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.
- you 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.
- you are already taking a blood pressure-lowering medicine that contains aliskiren **and** you have diabetes and/or kidney disease.
- you have heart problems, such as:
  - aortic stenosis, a narrowing of the aortic heart valve;
  - problems with the heart muscle (hypertrophic cardiomyopathy);
  - heart failure.
- you are pregnant, planning on becoming pregnant or able to become pregnant and are not using a reliable birth control method. Taking VIACORAM during pregnancy can cause injury and even death to your baby. If you discover that you are pregnant during treatment, stop taking VIACORAM and tell your healthcare professional **right away**.
- you are breast-feeding or planning to breast-feed. VIACORAM passes into breast milk.
- you have one of the following rare hereditary diseases:
  - Galactose intolerance
  - Lapp lactase deficiency
  - Glucose-galactose malabsorption

Because VIACORAM contains lactose.

**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 of African origin. You may have a higher risk of experiencing serious allergic reactions (angioedema) while taking VIACORAM.
- 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:
    - aliskiren
    - angiotensin receptor blockers (ARBs). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".
    - other ACE inhibitors
    - diuretics, also known as "water pills"
  - certain anti-cancer medicines (e.g., temsirolimus, everolimus)
  - 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 heartbeats
- have diabetes.
- have liver or kidney problems (including kidney transplantation).
- have, or have had a condition, that causes a decrease in blood flow to your heart or brain (e.g., ischemic heart or cerebrovascular disease, angina, coronary artery disease, heart attack, stroke).
- have an autoimmune disease that causes chronic inflammation to your skin, joints and/or blood vessels.
- 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 (e.g., spironolactone, eplerenone, triamterene or amiloride)
  - medicines affecting the immune system (e.g., cyclosporine, tacrolimus, sirolimus)
  - non-steroidal anti-inflammatory drugs (NSAIDs), used to treat pain, fever and inflammation
  - heparin, used to thin the blood and prevent blood clots
  - other medicines that may increase potassium in your blood (e.g., trimethoprim, which is an antibiotic often prescribed in combination with sulfamethoxazole)
- are on a low-salt diet.
- have been told by a healthcare professional that your blood is too acidic (metabolic acidosis).
- 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 LDL cholesterol in the blood).
- are receiving gold (sodium aurothiomalate) injections.
- are going to have surgery with anesthesia, including dental procedures.

**Other warnings you should know about:**

VIACORAM can cause serious side effects, including:

- **Allergic reaction and Angioedema:** Allergic reactions and angioedema (swelling of the face, lips, tongue, throat, digestive tract, genitals and/or difficulty breathing or swallowing) have happened in people taking VIACORAM. These side effects may happen at any time during treatment with VIACORAM, even if you have been taking it for a long period without problems. Very rarely, cases have been fatal. If you experience symptoms of an allergic reaction or angioedema, 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.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)
  - anemia (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 problemsYou 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 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.

**Testing and check-ups:** Your healthcare professional may do tests, including blood tests, before you take VIACORAM and/or during treatment. These tests will check:

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

- the potassium and sodium 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. Your healthcare professional may ask you to stop taking VIACORAM one day before your surgery. Follow their instructions exactly.

**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 used to lower your blood pressure. These include:
  - diuretics ("water pills")
  - aliskiren-containing medicines
  - angiotensin receptor blockers (ARBs)
  - other ACE inhibitors
  - calcium channel blockers (e.g., verapamil, diltiazem)
- medicines that can increase the levels of potassium in your blood. These include:
  - salt substitutes that contain potassium
  - potassium supplements
  - potassium-sparing medicines (e.g., spironolactone, eplerenone, triamterene, amiloride)
  - heparin, used to thin the blood and prevent blood clots
  - medicines affecting the immune system (e.g., cyclosporine, tacrolimus, sirolimus)
  - a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), used to reduce pain, fever and inflammation (e.g., acetylsalicylic acid, ibuprofen, naproxen, celecoxib)
- other medicines that may increase serum potassium (e.g., trimethoprim, which is an antibiotic often prescribed in combination with sulfamethoxazole)
- medicines used to treat diabetes. These include:
  - insulin
  - metformin or other antidiabetic medicines taken by mouth
  - a class of medicine called DPP-IV inhibitors (e.g., sitagliptin, linagliptin, saxagliptin)
- allopurinol, used to treat gout
- a class of medicines called vasodilators, including nitrates (e.g., nitroglycerin), used to treat chest pain
- procainamide, used to treat irregular heartbeats
- medicines to treat mental health problems such as bipolar disorder, depression, and psychotic disorders (e.g., lithium, tricyclic antidepressants, antipsychotics)
- medicines used to treat low blood pressure, shock and asthma (e.g., ephedrine, noradrenaline, adrenaline)
- baclofen, a muscle relaxant
- antibiotics, used to treat bacterial infections (e.g., rifampicin, erythromycin, clarithromycin)

- medicines used to treat epilepsy (e.g., carbamazepine)
- medicines used to treat fungal infections (e.g., itraconazole, ketoconazole)
- alpha-blockers used for the treatment of enlarged prostate (e.g., prazosin, alfuzosin, doxazosin, tamsulosin, terazosin)
- corticosteroids, used to treat inflammation
- gold (sodium aurothiomalate) injections, to treat rheumatoid arthritis
- medicines used to treat HIV/AIDS (e.g., ritonavir, indinavir)
- St John's wort, a herbal remedy
- simvastatin, used to lower cholesterol
- allergy shots for bee or wasp stings
- tetracosactide (also known as cosyntropin), used as a diagnostic agent
- medicines containing a neutral endopeptidase (NEP) inhibitor (e.g., sacubitril), used to treat heart failure
- treatments where a machine removes blood from your body, filters it and returns the cleaned blood to your body (known as extracorporeal treatments). These include:
  - dialysis or hemofiltration, a process that removes wastes from your body in place of your kidneys using polyacrylonitrile membranes
  - low-density lipoprotein (LDL) apheresis, a treatment that removes the cholesterol from your blood using dextran sulphate
- certain anti-cancer medicines (e.g., everolimus, temsirolimus, estramustine)
- anaesthetics, used to prevent pain during surgery
- grapefruit or grapefruit juice

#### **How to take VIACORAM:**

- Take VIACORAM:
  - exactly as prescribed.
  - once daily 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:**

Symptoms of an overdose with VIACORAM may include:

- low blood pressure
- fast heartbeat
- pulmonary edema (accumulation of fluids in the lungs) causing shortness of breath. This may develop up to 24 to 48 hours after taking too much VIACORAM.

If you think you, or a person you are caring for, have taken too much VIACORAM, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

#### **Missed dose:**

If you miss a dose of your medication, skip your missed dose and take the next dose at your usual scheduled time. Do not double your dose to make up for a missed dose.

**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 with VIACORAM may include:

- cough (often described as dry and irritating, usually is worse at night or when lying down)
- headache
- common cold symptoms (stuffy or runny nose, sore throat, fever)
- general feeling of discomfort
- diarrhea or constipation
- nausea or vomiting
- changes in bowel habits
- changes in weight
- dry mouth
- changes in your sense of taste
- indigestion
- dizziness or vertigo (feeling of spinning)
- fatigue, lack of energy, feeling sleepy
- trouble sleeping
- sensitivity to light, redness of the skin, rash, itching
- excessive sweating
- flushing
- tingling or “pins and needles” sensation of the skin
- back or abdominal pain
- muscle pain or spasms
- joint pain or swelling

**Serious side effects and what to do about them**

| Frequency/Side Effect/Symptom                                                                                                                    | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                  | Only if severe                       | In all cases |                                                      |
| Very common                                                                                                                                      |                                      |              |                                                      |
| Peripheral edema (swelling of the hands, ankles or feet caused by fluid retention): swollen or puffy legs or hands, feeling heavy, achy or stiff | X                                    |              |                                                      |
| Common                                                                                                                                           |                                      |              |                                                      |
| Hyperkalemia (too much potassium in the blood): irregular heartbeat, muscle weakness and generally feeling unwell                                |                                      | X            |                                                      |
| Persistent cough                                                                                                                                 |                                      | X            |                                                      |

| Frequency/Side Effect/Symptom                                                                                                                                                                                                                                                                                                                                     | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                   | Only if severe                       | In all cases |                                                      |
| Uncommon                                                                                                                                                                                                                                                                                                                                                          |                                      |              |                                                      |
| <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                                                                                             |                                      |              | X                                                    |
| <b>Blood disorders:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms, bruising, bleeding, weakness, small purple or red dots under the skin                                                                                                                                                                                                    |                                      | X            |                                                      |
| <b>Bronchospasm:</b> difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing                                                                                                                                                                                                                                               |                                      |              | X                                                    |
| <b>Worsening angina</b> (chest pain): discomfort in the shoulder, arm, back, throat, jaw or teeth, pain or pressure in the chest                                                                                                                                                                                                                                  |                                      | X            |                                                      |
| <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 |                                      |              | X                                                    |
| <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                                                                                       |                                      | X            |                                                      |

| Frequency/Side Effect/Symptom                                                                                                                                                                                                                                                                             | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                           | Only if severe                       | In all cases |                                                      |
| friends, reduced libido (sex drive) and thoughts of death or suicide                                                                                                                                                                                                                                      |                                      |              |                                                      |
| <b>Electrolyte imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat                                                                                                                                                                                                            |                                      | X            |                                                      |
| <b>Erectile dysfunction:</b> unable to get or keep an erection                                                                                                                                                                                                                                            | X                                    |              |                                                      |
| <b>Hyperglycemia</b> (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision, fatigue                                                                                                                                                                                | X                                    |              |                                                      |
| <b>Hypoglycemia</b> (low blood sugar): thirst, frequent urination, hunger, nausea and dizziness, fast heartbeat, tingling trembling, nervousness, sweating, low energy                                                                                                                                    |                                      | X            |                                                      |
| <b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.                                                                                                                                                               | X                                    |              |                                                      |
| <b>Kidney problems:</b> change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue                                                                                                                                                                                              |                                      | X            |                                                      |
| <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 |                                      |              | X                                                    |
| <b>Pemphigoid / Pemphigus:</b> blisters of different sizes develop on the skin                                                                                                                                                                                                                            |                                      |              | X                                                    |
| <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                                                                                                                                                           |                                      |              | X                                                    |

| Frequency/Side Effect/Symptom                                                                                                                                                                                                                                                                                                                                                          | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                        | Only if severe                       | In all cases |                                                      |
| 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>X</b>     |                                                      |
| <b>Worsening of psoriasis</b> (chronic skin disease): red, itchy, scaly patches of the skin                                                                                                                                                                                                                                                                                            |                                      | <b>X</b>     |                                                      |
| <b>Very rare</b>                                                                                                                                                                                                                                                                                                                                                                       |                                      |              |                                                      |
| <b>Liver problems:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite                                                                                                                                                                                                                                                                   |                                      | <b>X</b>     |                                                      |
| <b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea and vomiting, tenderness when touching the abdomen                                                                                                                                                                                                                            |                                      |              | <b>X</b>                                             |
| <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>X</b>                                             |
| <b>Unknown</b>                                                                                                                                                                                                                                                                                                                                                                         |                                      |              |                                                      |
| <b>Extrapyramidal symptoms:</b> muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want                                                                                                                                                                                                                         |                                      |              | <b>X</b>                                             |
| <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                                                                                                                                                                               |                                      | <b>X</b>     |                                                      |

| Frequency/Side Effect/Symptom                                                                                                                                                           | Talk to your healthcare professional |              | Stop taking this drug and get immediate medical help |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------|------------------------------------------------------|
|                                                                                                                                                                                         | Only if severe                       | In all cases |                                                      |
| <b>Arrhythmia</b> (abnormal heart rhythms): rapid, slow or irregular heartbeat                                                                                                          |                                      | X            |                                                      |
| <b>Urinary tract disorders:</b> difficulty and pain when passing urine, exaggerated sense of needing to urinate, blood in urine                                                         |                                      | X            |                                                      |
| <b>Erythema multiforme</b> (an allergic skin reaction): raised red or purple skin patches, possibly with blister or crust in the center, possibly swollen lips, mild itching or burning |                                      | X            |                                                      |

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 ([canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

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

#### 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 the Patient Medication Information by visiting the Health Canada Drug Product Database 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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