PART III: CONSUMER INFORMATION

PrVIACORAM®

perindopril arginine and amlodipine tablets

This leaflet is part III of a three-part "Product Monograph" published when VIACORAM was approved for sale in Canada and is designed specifically for consumers. 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 VIACORAM®. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about VIACORAM®.

ABOUT THIS MEDICATION

What the medication is used for:

VIACORAM® is used to treat mild to moderate high blood pressure. VIACORAM® should only be started in patients who are between the ages of 18 and 65.

What it does:

VIACORAM® is a combination of two active ingredients, perindopril arginine and amlodipine.

Perindopril arginine

- Is an angiotensin converting enzyme (ACE) inhibitor.
- ACE inhibitors help relax blood vessels and lower blood pressure by preventing ACE from producing angiotensin II which causes narrowing of blood vessels.

Amlodipine

- Is a calcium channel blocker.
- It blocks the transfer of calcium into the cells of the heart and blood vessels.
- This helps the blood vessels relax and to decrease blood pressure.

This medicine does not cure your disease. It is important to continue taking VIACORAM® regularly even if you feel fine. Do not stop taking your medicine without the advice of your doctor.

When it should not be used:

Do not take VIACORAM® if you:

- Are less than 18 years old.
- Are older than 65 and starting treatment.
- Are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to amlodipine or any other calcium antagonists, or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have kidney problems.
- Are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Have narrowing of the mitral valve and left ventricular outflow tract obstruction (aortic stenosis, hypertrophic cardiomyopathy).
  Have heart failure.
- Are pregnant or intend 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®.
- Are on dialysis or any other type of blood filtration. Depending on the machine that is used, VIACORAM® may not be suitable for you.
- Have kidney problems where the blood supply to your kidneys is significantly reduced (renal artery stenosis).

What the medicinal ingredient is:

perindopril arginine and amlodipine.

What the non-medicinal ingredients are:

Microcrystalline cellulose, lactose monohydrate, magnesium stearate, colloidal anhydrous silica.

What dosage forms it comes in:

VIACORAM® tablets are available in 3 combinations of perindopril/ amlodipine: 3.5 mg/2.5, 7 mg/5 mg, 14 mg/10 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
VIACORAM® should not be used during pregnancy. If you discover that you are pregnant while taking VIACORAM®, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use VIACORAM® talk to your doctor, nurse or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood).
- Have heart failure.
- Have a severe increase in blood pressure (hypertensive crisis).
- Are taking a medicine that contains aliskiren used to lower high blood pressure. The combination with VIACORAM® is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".
- Have diabetes, heart, liver or kidney disease (including kidney transplantation).
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Are on a low-salt diet.
- Are less than 18 years old or are older than 65.
- Have systemic lupus erythematosus (SLE).
- 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.

Monitoring: Your physician may monitor your blood and kidney function while taking VIACORAM®.

Surgery: If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking VIACORAM®.

Driving and using machines: Wait until you know how you feel while taking VIACORAM® before driving or using machines. Dizziness, headache, fatigue, nausea, weariness or fainting can occur, especially after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with VIACORAM®:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Allopurinol used to treat gout.
- Antidiabetic drugs, including insulin and oral medicines.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products, or angiotensin receptor blockers (ARBs).
- Lithium used to treat bipolar disorder.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include aspirin, ibuprofen, naproxen, and celecoxib.
- Vasodilators including nitrates (products that make the blood vessels become wider).
- Procainamide used to treat irregular heartbeats.
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics).
- Immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus).
- Heparin (medicines used to thin blood).
- Ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma).
- Baclofen used to treat muscle stiffness in diseases such as multiple sclerosis.
- Some antibiotics such as rifampicin, erythromycin, clarithromycin.
- Antiepileptic agents such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone,
- Itraconazole, ketoconazole (medicines used for treatment of fungal infections).
- Alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin).
- Corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis).
- Gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- Ritonavir, indinavir, nelfinavir (used to treat HIV).
- Trimethoprim (for the treatment of infections).
- Estramustine (used in cancer therapy).
- Hypericum perforatum (St John's wort, an herbal medicine used to treat depression).
- Simvastatin (a cholesterol lowering medicine).
- Anaesthetics.
- Treatment for bee and wasp allergies.
- Tetracosactide (used as a diagnostic agent in the clinic).

Grapefruit juice and grapefruit should not be consumed by

people who are taking VIACORAM®. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of VIACORAM®.

PROPER USE OF THIS MEDICATION

Take VIACORAM® exactly as prescribed.

Tablets should be swallowed whole with a glass of water preferably at the same time each day, **in the morning**. It is recommended to take your dose before a meal.

Usual Adult dose:
The initial recommended dose is one tablet of VIACORAM® 3.5 mg/2.5 mg once daily.

After a month of treatment, depending on how you respond to the treatment, your doctor may increase the dose to 7mg/5mg once a day.

If your blood pressure is not controlled after 1 month of treatment with 7 mg/5 mg dose, your doctor may prescribe the 14 mg/10 mg VIACORAM® tablet once daily.

One tablet of VIACORAM® 14 mg/10 mg once a day is the maximum recommended dose for high blood pressure.

Overdose:

If you think you have taken too much VIACORAM® contact your doctor, nurse, pharmacist, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, VIACORAM® can cause side effects, although not everybody gets them.

Side effects may include:

- cough,
- swelling in the tissues of the body (oedema),
- headache,
- diarrhea,
- nausea,
- dizziness,
- tiredness,
- itching (erythema).

If any of these affects you severely, tell your doctor, nurse or pharmacist.

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

Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	**Low Blood Pressure:** dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up.	√		
	Palpitations: unusual fast or irregular heartbeats			√
	Edema: swelling of the hands, ankles or feet	√		
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Uncommon	**Angina:** sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing			√
	Increased levels of potassium in the blood (hyperkalemia) : irregular heartbeat, muscle weakness and generally feeling unwell		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor, nurse, or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
	Angioedema and Severe Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Decreased Platelet: bruising, bleeding, fatigue and weakness		√	
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
	Cerebrovascular accident/Stroke: slurring speech, blurred vision, face drooping			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor, nurse, or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
Very rare	**Inflammation of the pancreas** (pancreatitis)**:** abdominal pain that lasts and gets worse when you lie down, nausea and vomiting			√
	Severe skin reactions (Steven-Johnson Syndrome): intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes.			√
	Liver problems: abdominal pain, nausea, vomiting, loss of appetite, jaundice (yellowing of eyes and skin).		√	
	Myocardial infarction: heart attack, chest pain			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor, nurse, or pharmacist**		**Stop taking drug and seek immediate medical help**
		Only if severe	**In all cases**	
Unknown	**Extrapyramidal disorder:** Muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.		√	
	Phemphigoid: formation of blister clusters over the skin			√

This is not a complete list of side effects. For any unexpected effects while taking VIACORAM®, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada vigilance Program**
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available in the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.servier.ca or by contacting the sponsor, Servier Canada Inc., at: 1-800-363-6093

This leaflet was prepared by Servier Canada Inc.
SERVIER CANADA INC.
235, Boulevard Armand Frappier
Laval, Québec
H7V 4A7

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