

VIACORAM tablets

Perindopril arginine/amlodipine

3.5mg/2.5mg, 7mg/5mg

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What VIACORAM is used for

VIACORAM is a combination of two active ingredients, perindopril and amlodipine. Both of these substances help to control your high blood pressure.

VIACORAM is used to treat mild to moderate high blood pressure (hypertension) in adults.

How VIACORAM works

Perindopril is an ACE (Angiotensin Converting Enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

Before you use VIACORAM

When you must not use it

Do not take VIACORAM:

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to amlodipine or any other calcium antagonists, or any of the other ingredients of this medicine (listed in ingredients section),
- if you have severe kidney problems,
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),

- if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body),
- if you have severe low blood pressure (hypotension),
- if you suffer from heart failure after a heart attack,
- if you are more than 3 months pregnant (it is also better to avoid VIACORAM in early pregnancy – see pregnancy section),
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren,
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, VIACORAM may not be suitable for you,
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you have taken or are currently taking sacubitril/valsartan, a medicine for heart failure, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see “Warning and Precautions” and “Taking other medicines”)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking VIACORAM before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of VIACORAM. VIACORAM is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. Tell your doctor if you are breast-feeding or about to start breast-feeding. VIACORAM is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

VIACORAM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Children and adolescents

VIACORAM should not be given to children and adolescents.

Before you start to use it

Warning and precautions

Talk to your doctor or pharmacist before taking VIACORAM if you:

- have hypertrophic cardiomyopathy (cardiac muscle disease),
- have heart failure,
- have severe increase in blood pressure (hypertensive crisis),
- have any other heart problems,
- have liver problems,
- have kidney problems (including kidney transplantation),
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- have collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- have diabetes,
- are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential),
- are elderly and your dose needs to be increased,
- are taking any of the following medicines used to treat high blood pressure:
 - o an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in

particular if you have diabetes-related kidney problems.

- o aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

- See also information under the heading “Do not take VIACORAM”.
- are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- are taking any of the following medicines, the risk of angioedema is increased:
 - o racecadotril (used to treat diarrhoea),
 - o sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer),
 - o sacubitril (available as fixed dose combination with valsartan) used to treat long-term heart failure,
 - o linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of gliptins (used to treat diabetes).

Angioedema:

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE inhibitors, including perindopril. This may occur at any time during treatment. If you develop such symptoms, you should stop taking VIACORAM and see a doctor immediately. See also Side effects section.

When you are taking VIACORAM, you should also inform your doctor or the medical staff if you:

- are going to have a general anaesthetic and/or major surgery,
- have recently suffered from diarrhoea or vomiting (being sick),
- are to undergo LDL apheresis (the removal of cholesterol from your blood by a machine),

- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should avoid VIACORAM with:

- lithium (used to treat mania or depression),
- estramustine (used in cancer therapy),
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin, medicine used to thin blood to prevent clots, trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for the treatment of infections and ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection),
- aliskiren (used to treat high blood pressure), (see also information under the headings “Do not take VIACORAM” and “Warnings and precautions”),
- angiotension II -receptor blockers (ARB) (used to treat high blood pressure) (e.g. valsartan, telmisartan, irbesartan...),
- dantrolene (infusion) (used to treat muscle stiffness in diseases such as multiple sclerosis or to treat malignant hyperthermia during anaesthesia, symptoms including very high fever and muscle stiffness),
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take VIACORAM” and “Warnings and precautions”.

Treatment with VIACORAM can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys),
- medicines, which are most often used to avoid rejection of transplanted

organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors). See section “Warnings and precautions”,

- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin, gliptins),
- 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),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that widen the blood vessels),
- 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,
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer),
- 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 (so called protease inhibitors used to treat HIV),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50 mg by day,
- trimethoprim and co-trimoxazole (for the treatment of infections),
- hypericum perforatum (St John's wort, an herbal medicine used to treat depression).

How to use VIACORAM

How much to use

Always take VIACORAM exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet of VIACORAM 3.5 mg/2.5 mg once daily.

If you suffer from moderate kidney problems, your doctor may advise you to take one tablet of VIACORAM 3.5 mg/2.5 mg every other day at the start of the treatment.

Depending on how you respond to the treatment, your doctor may decide to increase the dose after one month to VIACORAM 7 mg/5 mg once a day if required.

One tablet of VIACORAM 7 mg/5 mg once a day is the maximum recommended dose for high blood pressure

Do not exceed the prescribed dose.

When to use it

Take your tablet preferably at the same time each day, in the morning, before a meal.

How long to use it

Continue taking VIACORAM for as long as your doctor recommends.

If you forget to use it

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of VIACORAM, take the next dose at the usual time. Do not take a

double dose to make up for a forgotten dose.

If you use too much (overdose)

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with your legs raised can help.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things you must not do

As the treatment with VIACORAM is usually life-long, you should discuss with your doctor before you stop taking your tablets.

Things to be careful of

VIACORAM with food and drink

See "When to use it" section.

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.

Driving and using machines

VIACORAM may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicinal product and see a doctor immediately, if you

experience any of the following side effects that can be serious:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon),
- swelling of eyelids, face or lips (Uncommon),
- swelling of the tongue and throat, which causes great difficulty breathing (angioedema) (Uncommon),
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching (erythema multiforme) (Very rare), blistering, peeling and swelling of the skin (exfoliative dermatitis) (Very rare), inflammation of mucous membranes (Stevens Johnson Syndrome) (Very rare) or other allergic reactions (Uncommon),
- severe dizziness or fainting due to low blood pressure (Common),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (Very rare),
- heart attack, chest pain (angina) (Very rare), unusual fast or abnormal heart beat (Common),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare).

The following **side effects** have been reported with VIACORAM. If any of these cause you problems, you should

contact your doctor:

- Common (may affect up to 1 in 10 people): light-headedness, cough, oedema (fluid retention).
- Uncommon side effects (may affect up to 1 in 100 people): high levels of blood potassium which can cause abnormal heart rhythm (hyperkalaemia), excess sugar in the blood (hyperglycaemia), tiredness.

The following **side effects** have been reported with perindopril or amlodipine, and either not observed with VIACORAM or observed with a higher frequency than with VIACORAM. These side effects may also occur with VIACORAM. If any of these cause you

problems, you should **contact your doctor**:

- Very common side effects (may affect more than 1 in 10 people):
oedema (fluid retention).
- Common side effects (may affect up to 1 in 10 people):
headache, sleepiness (especially at the beginning of treatment), abnormal taste perception, numbness or tingling sensation in your limbs, vertigo, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), flushing, shortness of breath (dyspnoea), abdominal pain, nausea (feeling sick), vomiting (being sick), dyspepsia or difficulty of digestion, change of bowel habit, constipation, diarrhoea, itching, skin rashes, redness of the skin, pruritus, ankle swelling, muscle cramps, tiredness, weakness.
- Uncommon side effects (may affect up to 1 in 100 people):
increase in some white blood cells (eosinophilia), low sodium level in the blood (hyponatraemia), low sugar level in the blood (hypoglycaemia), mood swings, anxiety, sleeplessness, depression, sleep disturbances, syncope, loss of pain sensation, trembling, vasculitis (inflammation of blood vessels), rhinitis (blocked up or runny nose), dry mouth, increased sweating, hair loss, red patches on skin, skin discolouration, formation of blister clusters over the skin, sensitivity to light, back pain, muscle or joint pain, disorder in passing urine, increased need to urinate at night, increased number of times of passing urine, kidney problems, impotence, discomfort or enlargement of the breasts in men, chest pain, feeling unwell, pain, weight increase or decrease, increased blood urea, increased blood creatinine, fall, fever.
- Rare side effects (may affect up to 1 in 1000 people):
acute renal failure; symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion): dark urine, feeling sick (nausea) or being sick (vomiting),

muscle cramps, confusion and seizures; decreased or absent urine output; psoriasis worsening; high level of serum bilirubin; increased level of liver enzymes.

- Very rare side effects (may affect up to 1 in 10,000 people):
changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, increased muscle tension, disorders of the nerves which can cause weakness, tingling or numbness, eosinophilic pneumonia (a rare type of pneumonia), swelling of the gums, abdominal bloating (gastritis), yellowing of the skin (jaundice).
- Frequency not known (frequency cannot be estimated from the available data):
trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk, discolouration, numbness and pain in fingers or toes (Raynaud's phenomenon).

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors.

If you have these symptoms, contact your doctor as soon as possible.

Reporting of side effects

Tell your doctor/pharmacist if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of VIACORAM. Consult your doctor/pharmacist for further information.

Call your doctor for medical advice about side effects. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Viacoram

Storage

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Store below 30°C.


Once opened, VIACORAM should be used within 10 days for tablet containers of 10 tablets and 30 days for tablet containers of 30 tablets.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description

What it looks like:

VIACORAM 3.5 mg/2.5 mg tablets are white, round tablets, 5 mm diameter. VIACORAM 7 mg/5 mg tablets are white, round tablets, 6 mm diameter, engraved with  on one face.

The tablets are available in packs containing 10 or 30 tablets.

The dessicant is present in the stopper of the tablet containers.

Not all pack sizes may be marketed.

Ingredients

- Active ingredients:

The active substances are perindopril arginine and amlodipine.

One tablet of VIACORAM 3.5 mg/2.5 mg contains 2.378 mg perindopril equivalent to 3.5 mg perindopril arginine and 3.4675 mg amlodipine besilate equivalent to 2.5 mg amlodipine.

One tablet of VIACORAM 7 mg/5 mg contains 4.756 mg perindopril equivalent to 7 mg perindopril arginine and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.

- Other ingredients:

Lactose monohydrate, magnesium stearate (E470B), cellulose microcrystalline (E460), colloidal anhydrous silica (E551).

MAL number:

MAL 19016045AZ

MAL 19016046AZ

Manufacturer

Servier (Ireland) Industries Ltd

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Product registration holder

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