

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Viacoram 3.5 mg/2.5mg tablets**  
**Viacoram 7 mg/5 mg tablets**  
perindopril arginine / amlodipine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Viacoram is and what it is used for
2. What you need to know before you take Viacoram
3. How to take Viacoram
4. Possible side effects
5. How to store Viacoram
6. Contents of the pack and other information

### **1. What Viacoram is and what it 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.

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.

Viacoram is used to treat high blood pressure (hypertension) in adults.

### **2. What you need to know before you take Viacoram**

#### **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 section 6),
- 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 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).

### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse 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:
  - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs).

#### 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 section 4.

You must tell your doctor if you think you are (or might become) pregnant. Viacoram is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy 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 going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

### **Children and adolescents**

Viacoram should not be given to children and adolescents.

### **Other medicines and Viacoram**

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),
- medicines, which is 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”,
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- 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).

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),
- 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. ciclosporine, 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 (for infection caused by bacteria),
- 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),
- estramustine (used in cancer therapy),
- hypericum perforatum (St John’s wort, an herbal medicine used to treat depression).

### **Viacoram with food and drink**

See section 3.

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.

### **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.

**Breastfeeding**

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.

**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.

**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.

**3. How to take Viacoram**

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.

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

Do not exceed the prescribed dose.

**If you take more Viacoram than you should**

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.

**If you forget to take Viacoram**

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 stop taking Viacoram**

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

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

#### 4. Possible 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– may affect up to 1 in 100 people),
- swelling of eyelids, face or lips (Uncommon- may affect up to 1 in 100 people),
- swelling of the tongue and throat, which causes great difficulty breathing (angioedema) (Uncommon– may affect up to 1 in 100 people),
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching (erythema multiforme) (Very rare - may affect up to 1 in 10,000 people), blistering, peeling and swelling of the skin (exfoliative dermatitis) (Very rare - may affect up to 1 in 10,000 people), inflammation of mucous membranes (Stevens Johnson Syndrome) (Very rare- may affect up to 1 in 10,000 people) or other allergic reactions (Uncommon - may affect up to 1 in 100 people),
- severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (Very rare - may affect up to 1 in 10,000 people),
- heart attack, chest pain (angina) (Very rare - may affect up to 1 in 10,000 people), unusual fast or abnormal heart beat (Common - may affect up to 1 in 10 people),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (Very rare - may affect up to 1 in 10,000 people),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare - may affect up to 1 in 10,000 people).

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.

- Rare side effects (may affect up to 1 in 1000 people): confusion, 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), acute renal failure.
- Frequency not known (frequency cannot be estimated from the available data): trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk, 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. If you have these symptoms contact your doctor as soon as possible.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V\*. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Viacoram**

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.

This medicine does not require any special storage conditions.

Once opened, Viacoram should be used within 10 days for tablet containers of 10 tablets, 30 days for tablet containers of 30 tablets, 50 days for tablet containers of 50 tablets and 90 days for tablet containers of 100 tablets.

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.


## **6. Contents of the pack and other information**

### **What Viacoram contains:**

- 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.
- The other ingredients are: lactose monohydrate, magnesium stearate (E470B), cellulose microcrystalline (E460), colloidal anhydrous silica (E551).

### **What Viacoram looks like and contents of the pack:**

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 of Viacoram 3.5 mg/2.5 mg and Viacoram 7 mg/5 mg are available in packs containing 10, 30, 60 (2 tablet containers of 30), 90 (3 tablet containers of 30), 100 (2 tablet containers of 50), 100 or 500 (5 tablet containers of 100) tablets.

The dessicant is present in the stopper of the tablet containers.  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

<[To be completed nationally]>

For RMS (Italy):  
Les Laboratoires Servier  
50, rue Carnot  
92284 Suresnes cedex - France

#### **Manufacturer:**

Servier (Ireland) Industries Ltd  
Gorey Road  
Arklow - Co. Wicklow – Ireland

and

Les Laboratoires Servier Industrie  
905, route de Saran  
45520 Gidy - France

and

Anpharm Przedsiębiorstwo Farmaceutyczne S.A.  
Ul. Annopol 6B  
03-236 Warsaw – Poland

and

Egis Pharmaceuticals Private Limited Company  
Site 3: H-9900, Kőrmend  
Mátyás király u. 65. – Hungary

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria	Viacoram, Tabletten
Belgium	Viacoram, comprimé
Bulgaria	Prestarium Co start, таблетки
Croatia	Viacoram, tablete
Cyprus	Viacoram, δισκία
Czech Republic	Prestalia, tablety
Denmark	Viacoram
Estonia	Viacoram
Finland	Viacoram, tabletti
France	Amplival, comprimé
Germany	Viacoram, Tabletten
Greece	Viacoram, δισκία
Hungary	Viacoram tableta
Ireland	Viacoram, tablet
Italy	Viacoram, compresse

Latvia	Viacoram, tabletes
Lithuania	Viacoram, tabletės
Luxembourg	Viacoram, comprimé
Malta	Viacoram, tablet
Netherlands	Viacoram, tabletten
Poland	Co-Prestarium Initio
Portugal	Viacoram
Romania	Viacoram, comprimate
Slovakia	Viacoram, tablety
Slovenia	Viacoram tablete
Spain	Viacoram comprimidos

**This leaflet was last revised in {MM/YYYY}.**

[To be completed nationally]

**<Other sources of information>**

<Detailed information on this medicine is available on the website of {MS/Agency}>