

Package leaflet: Information for the patient

Amlodipine Viatris 5 mg Tablets **Amlodipine Viatris 10 mg Tablets** 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 or pharmacist.
- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Amlodipine Viatris is and what it is used for

Amlodipine tablets contain amlodipine, which belongs to a group of medicines called calcium antagonists.

Amlodipine is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, amlodipine works by improving blood supply to the heart muscle, which then receives more oxygen and as a result chest pain is prevented. Your medicine does not provide immediate relief of chest pain from angina.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Amlodipine Viatris

Do not take Amlodipine Viatris:

- If you are allergic to amlodipine or any of the other ingredients of this medicine (listed in section 6), or to any other calcium antagonists.
- If you have severe low blood pressure (hypotension).
- If the blood flow from the left side of your heart is obstructed (e.g. if you have narrowing of the aortic heart valve (aortic stenosis)).
- If you suffer from heart failure after a heart attack.
- If you suffer from cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlodipine if you have, or have had, any of the following conditions:

- Heart failure.

- Severe increase in blood pressure (Hypertensive crisis).
- Liver disease.

During treatment

Talk to your doctor:

- If you are elderly and your dose needs to be increased as special care needs to be taken when dosage is increased in elderly patients.

Children and adolescents

Amlodipine has not been studied in children under the age of 6 years. Amlodipine Viartis should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3).

For more information, talk to your doctor.

Other medicines and Amlodipine Viartis

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

Amlodipine may affect or be affected by other medicines, such as:

- anti-fungal medicines (e.g. ketoconazole, itraconazole)
- so called protease inhibitors used to treat HIV (e.g. ritonavir, indinavir, nelfinavir)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- hypericum perforatum (St. John's wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (a medicine to reduce blood cholesterol levels)
- tacrolimus, sirolimus, temsirolimus, and everolimus (medicines used to change the way your immune system works). Amlodipine may increase the levels of these medicines in your blood.
- ciclosporin (if you have had a kidney transplant and are taking ciclosporin) as amlodipine may alter the amount of this medicine in your blood

Amlodipine may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Amlodipine Viartis with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking amlodipine. 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 amlodipine.

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.

The safety of amlodipine in human pregnancy has not been established.

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking this medicine. Your doctor will only recommend you take this medicine if the benefits of the treatment outweigh any risks to the baby.

Driving and using machines

Amlodipine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines. These side effects may occur especially at the beginning of the treatment.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Amlodipine Viatris

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

The recommended initial dose is Amlodipine Viatris 5 mg once daily. The dose can be increased to Amlodipine Viatris 10 mg once daily.

Your medicine can be taken before or after food and drinks. You should take your medicine at the same time each day with a drink of water.

Patients with liver problems

Your doctor may ask you to take a lower dose and carry out frequent checks, if you are suffering from liver problems.

Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.

The tablet can be divided into equal doses.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

If you take more Amlodipine Viatris than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak or have a rapid heart beat. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake. Seek immediate medical attention if you take too many Amlodipine Viatris tablets.

If you forget to take Amlodipine Viatris

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlodipine Viatris

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

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.

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:

- Swelling of eyelids, face lips, tongue and throat which causes great difficulty in breathing or swallowing
- Severe skin reactions including 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 (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal or irregular heart beat, faster heart rhythm
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
- Yellowing of the skin or eyes, pale stools, dark urine or stomach pain (these may be signs of liver problems such as inflammation of the liver (hepatitis) or jaundice).
- Difficulty in speaking or swallowing, loss of balance control, mask-like face, shuffling walk, stiffness of arms and legs, trembling or shaking of hands or fingers (extrapyramidal syndrome).

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- Swelling which may be due to retention of fluid in the tissues

Common (may affect up to 1 in 10 people):

- Headache, dizziness, sleepiness, (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea), altered bowel habits which includes diarrhoea and constipation, indigestion
- Ankle swelling, tiredness, unusual weakness
- Visual disturbances including double vision
- Shortness of breath, muscle cramps

Uncommon (may affect up to 1 in 100 people):

- Mood changes (including feeling anxious), feeling depressed, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; decreased sensation
- Ringing in the ears
- Decreased heart rate
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis), cough
- Dry mouth, vomiting (being sick)
- Hair-loss, increased sweating, itchy skin, red patches on skin, skin discolouration, rash and hives, purple patches on the skin
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Pain, chest pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease

Rare (may affect up to 1 in 1,000 people):

- Confusion

Very rare (may affect up to 1 in 10,000 people):

- An increase in infections or fever eg. sore throat, mouth ulcers that you get (due to decreased number of white blood cells), or if you notice that you bruise or bleed more easily or without explanation (due to decrease in the number of blood platelets)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness

- Swelling of the gums
- Bleeding of the gums (gingival bleeding)
- Abdominal bloating (gastritis)
- Liver enzyme increase which may be due to liver problems such as blockage in the bile duct
- ‘Measles’ like skin rash. This may be associated with a high fever and joint pains (erythema multiforme)
- Peeling of the skin over large areas of the body
- Inflammation of blood vessels, often with skin rash
- Skin sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Amlodipine Viatris

Keep this medicine out of the sight and reach of children.

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

Store in the original package in order to protect from light.

Do not use this medicine if you notice any discolouration of the 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 Amlodipine Viatris contains

- The active substance is amlodipine.
- Each tablet contains 5 mg or 10 mg of amlodipine (as besilate)
- The other ingredients are calcium hydrogen phosphate, cellulose microcrystalline, sodium starch glycolate (type A), magnesium stearate.

What Amlodipine Viatris looks like and contents of the pack

Amlodipine Viatris 5 mg tablets are white coloured, round biconvex tablets debossed with “5” on one side and scored on the other side. The tablet can be divided into equal doses.

Amlodipine Viatris 10 mg tablets are white coloured, round biconvex tablets debossed with “10” on one side and scored on the other side. The tablet can be divided into equal doses.

Amlodipine Viatris tablets are packed in blisters containing 10, 14, 28, 30, 50, 56, 60, 90, 100, 180 tablets per pack.

Amlodipine Viatris tablets are packed in bottles containing 28, 30, 56, 100, 180, 500 tablets per pack.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Viartis Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland.

Manufacturer:

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.
Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary
Viartis UK Healthcare Limited, Building 20, Station Close, Potters Bar, EN6 1TL, United Kingdom

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

| | |
|-----------------|---|
| Belgium | Amlodipine besilate Viartis 5 mg tabletten Amlodipine besilate Viartis 10 mg tabletten |
| Czech Republic | Amlodipin Viartis 5 mg, tablety Amlodipin Viartis 10 mg, tablety |
| Germany | Amlodipin dura B 5 mg Tabletten Amlodipin dura B 10 mg Tabletten |
| Ireland | Amlodipine Viartis 5 mg tablets Amlodipine Viartis 10 mg tablets |
| Italy | Amlodipina Mylan 5 mg compresse Amlodipina Mylan 10 mg compresse |
| Poland | Amlomyl |
| Spain | Amlodipino Viartis 5 mg comprimidos EFG Amlodipino Viartis 10 mg comprimidos EFG |
| The Netherlands | Amlodipine (als besilaat) Viartis 5 mg tabletten Amlodipine (als besilaat) Viartis 10 mg tabletten |
| United Kingdom | Amlodipine 5 mg tablets Amlodipine 10 mg tablets |

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