

Package leaflet: Information for the user

/.../ 5 mg tablets

/.../ 10 mg tablets

Amlodipine (in the form of amlodipine besilate)

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

1. What /.../ is and what it is used for

/.../ contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

/.../ 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 /.../ 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.

2. What you need to know before you take /.../

Do not take /.../

- If you are allergic (hypersensitive) to amlodipine or any of the other ingredients of this medicine (listed in section 6), or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have severe low blood pressure (hypotension)

- 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 suffer from heart failure after a heart attack

Warning and precautions

Talk to your doctor or pharmacist before taking /.../

- if you have or have had recent heart attack
- if you have or have had heart failure
- if you have or have had severe increase in blood pressure (Hypertensive crisis)
- if you have or have had liver disease
- if you are elderly and your dose needs to be increased

Children and adolescents

/.../ has not been studied in children under the age of 6 years. /.../ 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 /.../

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

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

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (a cholesterol lowering medicine)

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

/.../ with food, drink and alcohol

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

Pregnancy, breast feeding and fertility

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take /.../.

Breast-feeding

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking /.../.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

/.../ 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 and contact your doctor immediately.

3. How to take /.../

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

The recommended dose is /.../ 5 mg once daily. The dose can be increased to /.../ 10 mg once daily.

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. Do not take /.../ with grapefruit juice.

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. Amlodipine 2.5 mg is not currently available and the 2.5 mg dose cannot be obtained with /.../ 5 mg tablets as these tablets are not manufactured to break into two equal halves.

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

If you take more /.../ 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. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many /.../ tablets.

If you forget to take /.../

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

If you stop taking /.../

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.

Visit your doctor **immediately** if you experience any of the following very rare, severe side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- 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) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

Common: affects 1 to 10 users in 100

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle swelling (oedema), tiredness

Other side-effects that have been reported include the following list. If any of these get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: affects 1 to 10 users in 1,000

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Visual disturbances, double vision, ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Altered bowel habits, diarrhoea, constipation, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- 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
- Weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain

- Weight increase or decrease

Rare: affects 1 to 10 users in 10,000

- Confusion

Very rare: affects less than 1 user in 10,000

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Cough, swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please **tell** your doctor or pharmacist.

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 /.../

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

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Tablets

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

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 to protect the environment.

6. Contents of the pack and other information

What /.../ contains

The active substance in /.../ 5 mg tablets is amlodipine (as besilate).

The active substance in /.../ 10 mg tablets is amlodipine (as besilate).

The other ingredients are Cellulose microcrystalline, Silica colloidal anhydrous and Magnesium stearate.

What /.../ contains

5 mg tablets

White to off white round shaped, biconvex tablets of diameter 7 mm, debossed with 'J' on one side and '20' on the other side.

10 mg tablets

White to off white round shaped, biconvex tablets of diameter 8 mm, debossed with 'J' on one side and '21' on the other side.

/.../ is supplied in the following pack sizes:

/.../ 5 mg tablets and /.../ 10 mg tablets are packed in Alu/PVC/PVdC blister and PVC/Alu/OPA/Alu blister.

Pack sizes: 4, 7, 10, 14, 15, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100, 112, 120, 180, 200, 250, 300, 500, 1 000 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

For PT:

Dr. Max Pharma Ltd.

First Floor Roxbourgh House, 273-287 Regent Street

London W1B 2HA

United Kingdom

For CZ, SK and PL:

Medreg s.r.o

Krčmářovská 223/33

196 00 Praha

Czech Republic

Manufacturer

Dr. Müller Pharma s.r.o.

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Průmyslová 961/16, 747 23 Bolatice
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Malta

This medicinal product is authorised in the Member States of the EEA under the following names:
<To be completed nationally>

This leaflet was last revised in MM/YYYY.