# BIJSLUITER: INFORMATIE VOOR DE GEBRUIKER

## Amlodipine CT 5 mg, tabletten
## Amlodipine CT 10 mg, tabletten

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

## 1. What Amlodipine tablets is and what it is used for

Amlodipine tablets contain the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

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

## 2. What you need to know before you take Amlodipine tablets

**Do not take Amlodipine tablets**

- 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. 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.

**Warnings and precautions**

*Talk to your doctor or pharmacist before taking Amlodipine tablets.*

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly and your dose needs to be increased.

**Children and adolescents**
Amlodipine has not been studied in children under the age of 6 years. Amlodipine tablets 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 tablets**

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

Amlodipine tablets 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, for infections caused by bacteria)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant).

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

**Amlodipine tablets with food and drink**
Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine tablets. 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 tablets.

**Pregnancy and breast-feeding**
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 Amlodipine tablets.

Breast-feeding
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 Amlodipine tablets.

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

**Driving and using machines**
Amlodipine tablets 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.

**Amlodipine tablets contain sodium**
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 3. How to take Amlodipine tablets

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

**Dosage**
***Amlodipine tablets 5 mg***
The recommended initial dose is 1 tablet (corresponding to 5 mg amlodipine) once daily. The dose can be increased to 2 tablets (corresponding to 10 mg amlodipine) once daily.

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

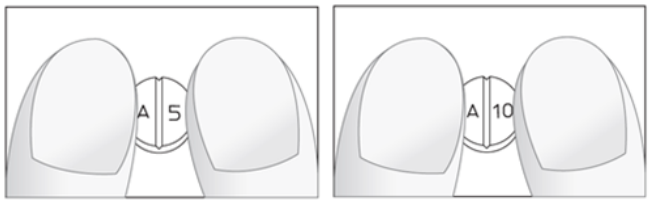
**Use in children and adolescents**
For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day.
The 2.5 mg dose can be obtained with Amlodipine tablets 5 mg as these tablets can be divided into equal doses.

***Amlodipine tablets 10 mg***
The recommended initial dose is ½ tablet (corresponding to 5 mg amlodipine) once daily. The dose can be increased to 1 tablet (corresponding to 10 mg amlodipine) once daily.

This medicine can be used before or after food and drinks. You should take this medicine at the same time each day with a drink of water. Do not take Amlodipine tablets 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.
The 2.5 mg dose cannot be obtained with Amlodipine tablets 10 mg.

**Amlodipine tablets can be divided into equal doses**
If you have been told by your doctor to take ½ (half) a tablet daily, we suggest not to use any device for halving. Please refer to the following instruction on how to break the tablet:
Place the tablet onto a flat, hard surface (e.g. a table or worktop), with the inscription upwards. Break the tablet by pushing it with the index fingers of both hands placed along the breakline.




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 tablets 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.
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 tablets.

**If you forget to take Amlodipine tablets**
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 tablets**
Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this 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 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, toxic epidermal necrolysis) 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 **very common side effect** has been reported. If this causes you problems or if it **lasts for more than one week**, you should **contact your doctor**.

**Very common**: may affect more than 1 in 10 people
– Oedema (fluid retention)

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**: 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, diarrhoea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

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:** may affect up to 1 in 100 people
- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs, loss of pain sensation
- Ringing in the ears
- 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
- 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, 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
- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause muscular weakness, tingling or numbness
- Swelling of the gums, bleeding 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

**Not known:** frequency cannot be estimated from the available data
- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

**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 Amlodipine tablets

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.
Store in the original package in order to protect from light and moisture.

HDPE bottle:
Shelf life after first opening: 4 months

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 tablets contains**

- The active substance is amlodipine.
  *Amlodipine tablets 5 mg*
  Each tablet contains 5 mg amlodipine (as besilate)
  *Amlodipine tablets 10 mg*
  Each tablet contains 10 mg amlodipine (as besilate)

- The other ingredients are microcrystalline cellulose (E 460), calcium hydrogen phosphate (E 341), sodium starch glycolate (Type A), magnesium stearate (E 470b).

**What Amlodipine tablets looks like and contents of the pack**

*Amlodipine tablets 5 mg*
White, round tablets. One side is slightly concave with a breakline and debossed “A5”. The other side is slightly convex and plain.

*Amlodipine tablets 10 mg*
White, round tablets. One side is slightly concave with a breakline and debossed “A10”. The other side is slightly convex and plain.

They are available in PVC/PVDC/Al blister packs with 10, 14, 20, 28, 30, 30x1, 50, 50x1, 56, 60, 90, 98, 100, 100x1, 200, 250 tablets.
They are available in HDPE bottles with 100 tablets.

Not all pack sizes may be marketed.

**Houder van de vergunning voor het in de handel bengen en fabrikant**
*Houder van de vergunning voor het in de handel brengen*
Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
Nederland

*Fabrikant*
Merckle GmbH
Ludwig-Merckle Strasse 3
89143 Blaubeuren
Duitsland

TEVA Pharmaceutical Works Ltd
Pallagi Ut 13
4042 Debrecen
Hongarije

Teva Pharma S.L.U.
C/C, n. 4, Poligono Industrial Malpica
50016 Zaragoza
Spanje

**In het register ingeschreven onder**
RVG 31809 - Amlodipine CT 5 mg, tabletten
RVG 31810 - Amlodipine CT 10 mg, tabletten

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**
Duitsland: Amlodipin-CT 5, 10 mg N Tabletten
Nederland: Amlodipine CT 5, 10 mg, tabletten

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2023**