

Package leaflet: information for the user

amlodipino cinfa 5 mg tablets

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 medicinal product has been prescribed for you. 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 amlodipino cinfa is and what it is used for
2. What you need to know before you take amlodipino cinfa
3. How to take amlodipino cinfa
4. Possible side effects
5. How to store amlodipino cinfa
6. Contents of the pack and other information

1. What amlodipino cinfa is and what it is used for

Amlodipino cinfa contains the active substance amlodipine, which belongs to a group of drugs known as calcium antagonists.

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

2. What you need to know before you take amlodipino cinfa

Do not take amlodipino cinfa

- 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 breathing.
- If you have severe low blood pressure (hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (an illness where your heart is unable to pump 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 amlodipino cinfa.

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 6 years of age. Amlodipine should only be used to treat arterial hypertension in children and adolescents from 6 to 17 years of age (see section 3). For more information, talk to your doctor.

Other medicines and amlodipino cinfa

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:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (also called protease inhibitors, used to treat AIDS)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- *Hypericum perforatum* (St John's wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus and everolimus (medicine used to modify the immune system)
- simvastatin (medicine that lowers cholesterol)
- ciclosporin (an immunosuppressant)

If you are already taking other medicines to treat your high blood pressure, amlodipine may lower your blood pressure even more.

Amlodipino cinfa 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 substance 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.

Pregnancy

The safety of amlodipine during pregnancy has not been established.

Breast-feeding

Small amounts of amlodipine have been shown to pass into breast milk. If you are breast-feeding, or about to start breast-feeding, you must tell your doctor before taking amlodipine.

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

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 and contact your doctor immediately.

Amlodipino cinfa contains sodium.

This medicine contains less than 23 mg (1 mmol) of sodium per tablet, i.e. it is essentially "sodium-free".

3. How to take amlodipino cinfa

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 5 mg of amlodipine once a day. The dose can be increased to 10 mg of amlodipine once a day.

This medicine can be taken before or after meals. You should take it at the same time each day with a glass of water. Do not take amlodipine with grapefruit juice.

Use in children and adolescents

For children and adolescents (6-17 years old), the normally recommended initial 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 amlodipino cinfa 5 mg tablets, as these tablets are not manufactured to be divided into equal halves. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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

If you take more amlodipino cinfa than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, dazed, faint when you get up or weak. If the drop in blood pressure is severe enough, shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

If you forget to take amlodipino cinfa

Do not worry. If you forget to take a tablet, do not take that dose. 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 amlodipino cinfa

Your doctor will tell you how long to take this medicine. Your condition may recur if you stop using this medicine before your doctor tells you.

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.

Report to your doctor **immediately** if you experience any of the following side effects after taking this medicine.

- Sudden wheezing, chest pain, shortness of breath or difficulty breathing
- Swelling of the 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 inflammation of the skin, inflammation of mucous membranes (Stevens–Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal heartbeat
- Inflammation of the pancreas, which may cause severe abdominal and back pain accompanied by 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, contact your doctor.

Very common (may affect more than 1 in 10 patients)

- Oedema (fluid retention).

The following **common side effects** have been reported. If any of these causes you problems or last for more than a week, contact your doctor.

Common (may affect up to 1 in 10 patients)

- Headache, dizziness, drowsiness (especially at the beginning of treatment)
- Palpitations (awareness of your heartbeat), 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 are included in the following list. 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.

Uncommon (may affect up to 1 in 100 patients)

- Mood changes, anxiety, depression, insomnia
- Tremor, taste abnormalities, fainting
- Numbness or tingling sensation in the limbs, loss of pain sensation
- Ringing in the ears
- Low blood pressure
- Sneezing/runny 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 the skin, skin discolouration
- Problems passing urine, increased need to urinate at night, increased frequency 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 gain or loss

Rare (may affect up to 1 in 1,000 patients)

- Confusion

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

- Decrease in the number of white blood cells, decrease in blood platelets, which may result in easy bleeding or unusual bruising
- Excess sugar in the blood (hyperglycaemia)
- A disorder of the nerves that can cause muscle weakness, tingling or numbness
- Inflamed gums
- Abdominal bloating (gastritis)
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), increase in liver enzymes, which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of the blood vessels, often with skin rash

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store amlodipino cinfa

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

Do not store above 25°C.

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 amlodipino cinfa contains

- The active substance is amlodipine. Each tablet contains 5 mg of amlodipine.
- The other ingredients are: microcrystalline cellulose, calcium hydrogen phosphate, sodium carboxymethyl starch (type A) (potato starch) and magnesium stearate.

What amlodipino cinfa looks like and contents of the pack

amlodipino cinfa is supplied as white, round scored tablets in PVC/Aluminium blisters in packs of 30 or 500 (clinical pack) tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta.
31620 - Huarte (Navarre), Spain

Manufacturers

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta
31620 - Huarte (Navarre), Spain.

or

Adamed Pharma, S.A.
ul. Marszałka J. Piłsudskiego 5
95-200 Pabianice
Poland

This leaflet was last revised in July 2019

Detailed information on this medicine is available on the website of the Spanish Agency for Medicines and Medical Devices (AEMPS) <http://www.aemps.gob.es/>.

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Warnings and precautions

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- Swelling of the 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 inflammation of the skin, inflammation of mucous membranes (Stevens–Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
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- Inflammation of the pancreas, which may cause severe abdominal and back pain accompanied by feeling very unwell.

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Very common (may affect more than 1 in 10 patients)

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- Ringing in the ears
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- Cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on the skin, skin discolouration
- Problems passing urine, increased need to urinate at night, increased frequency of passing urine
- Inability to obtain an erection, discomfort or enlargement of the breasts in men
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- Joint or muscle pain, back pain
- Weight gain or loss

Rare (may affect up to 1 in 1,000 patients)

- Confusion

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

- Decrease in the number of white blood cells, decrease in blood platelets, which may result in easy bleeding or unusual bruising
- Excess sugar in the blood (hyperglycaemia)
- A disorder of the nerves that can cause muscle weakness, tingling or numbness
- Inflamed gums
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- Sensitivity to light

- Disorders combining rigidity, tremor and/or movement disorders

Reporting of side effects

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5. How to store amlodipine cinfa

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