

AMLODIPINE MEDIS® 5 mg, scored film-coated tablets

AMLODIPINE MEDIS® 10 mg, scored film-coated tablets

(Amlodipine Besylate)

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 symptoms are the same as yours.
- If you get any 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 :

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- 1. What AMLODIPINE MEDIS scored film-coated tablets are and what they are used for**
- AMLODIPINE MEDIS scored film-coated tablets belongs to a group of medicines called calcium antagonists. AMLODIPINE MEDIS scored film-coated tablets are used to treat:
- High blood pressure (hypertension)
 - Chronic stable angina - vasospastic angina (Prinzmetal syndrome)
 - What you need to know before you take AMLODIPINE MEDIS scored film-coated tablets
- Do not take AMLODIPINE MEDIS scored film-coated tablets, 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 (the so-called dihydropyridines) like felodipine, nifedipine, nimodipine). This may be itching, reddening of the skin or difficulty in breathing.
 - are suffering from cardiogenic shock. This is a condition where the heart is unable to pump sufficient blood around the body. The symptoms of cardiogenic shock are low blood pressure, low pulse and fast heartbeat.
 - are suffering from 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) or if you suffer from heart failure after a heart attack.
 - suffer from chest pain at rest or with minimal effort (unstable angina pectoris).
 - are pregnant or breast-feeding
 - have severe low blood pressure (hypotension).
- Warnings and precautions**
- Before taking AMLODIPINE MEDIS scored film-coated tablets, tell your doctor if you**
- have heart failure or have suffered a heart attack during the past month.
 - Heart failure
 - Severe increase in blood pressure (Hypertensive crisis)
 - have liver problems
 - are giving this medicine to a child under 18 years of age
 - are elderly, your doctor may monitor you closely.

Children and adolescents

AMLODIPINE MEDIS has not been studied in children under the age of 6 years. AMLODIPINE MEDIS 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 MEDIS scored film-coated tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines (including medicines obtained without prescription, herbal medications or natural products) may interact with AMLODIPINE MEDIS. This means that the action of both medicines can be changed.

- Medicines that can lower blood pressure (e.g. verapamil, diltiazem)
- Ketoneconazole and itraconazole (antifungal medicines used to treat skin and fungal infections)
- HIV-protease-inhibitors (antiviral medicines used to treat HIV infections, e.g. ritonavir)
- Clarithromycin, erythromycin and telithromycin, rifampicin, rifabutin (antibiotics)
- Nefedipine (medicine to treat hypertension)
- St. John's wort (Hypericum perforatum; herbal medicine for depression)
- Dexamethasone (corticosteroid used to treat inflammatory and autoimmune conditions such as rheumatoid arthritis)

- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus (medicine used to alter the way your immune system works)
- simvastatin (cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)
- Phenytoin, phenytoin and carbamazepine (medicines for epilepsy)
- Ritonavir, Indinavir, Nelfinavir, Nevirapine (antiviral medicine used to treat HIV and AIDS)
- Sildenafil (medicine for impotence)

AMLODIPINE MEDIS scored film-coated tablets may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Taking AMLODIPINE MEDIS scored film-coated tablets with food and drink

AMLODIPINE MEDIS scored film-coated tablets should be taken with a glass of liquid (e.g. a glass of water) with or without food.

Grapefruit juice and grapefruit should not be consumed by people who are taking AMLODIPINE MEDIS scored film-coated tablets.

This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient AMLODIPINE MEDIS, which can cause an unpredictable increase in the blood pressure lowering effect of AMLODIPINE MEDIS.

Pregnancy and breast-feeding

Pregnancy

The safety of AMLODIPINE MEDIS 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 MEDIS scored film-coated tablets.

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Breast-feeding

AMLODIPINE MEDIS has been shown to pass into breast milk in small amounts. If you are breastfeeding or about to start breast-feeding you must tell your doctor before taking AMLODIPINE MEDIS scored film-coated tablets.

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

Driving and using machines

AMLODIPINE MEDIS scored film-coated 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.

Such side effects are more likely to occur at the start of treatment or following an increase in dose.

If you suffer from these effects, you should not drive or perform other activities that require you to be alert.

3. How to take AMLODIPINE MEDIS scored film-coated tablets

Dosage

Always take AMLODIPINE MEDIS scored film-coated tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Methods and routes of administration

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 MEDIS with grapefruit juice.

Adults

The usual starting dose is 5 mg once daily. If necessary, your doctor may increase the dose to 10 mg once daily.

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

Elderly patients

There is no special dosage for the elderly; however, care must be taken when the dose is increased.

If you have kidney problems

The normal dosage is recommended. AMLODIPINE MEDIS cannot be removed from the blood by dialysis (artificial kidney).

AMLODIPINE MEDIS scored film-coated tablets should be administered with particular caution to patients undergoing dialysis.

If you have liver problems

If you doctor will decide if this medicine is suitable for you and the correct dose for you to take.

If you take more AMLODIPINE MEDIS scored film-coated tablets than you should

If you or someone else has taken too much AMLODIPINE MEDIS, contact your nearest hospital casualty department. Please carry with you the product leaflet or remaining tablets for better identification of the product. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions, for example). Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed, faint or weak, problems with breathing, having to urinate very often, if blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

If you forget to take AMLODIPINE MEDIS scored film-coated 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 MEDIS scored film-coated 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, AMLODIPINE MEDIS scored film-coated tablets can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- 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 (≥ 1%)

- Oedema (fluid retention)

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

Common (≥ 10%)

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick/nausea
- Altered bowel habits, diarrhea, constipation, indigestion,
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Swollen ankles

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 (≥ 10,000)

- Enlarged breasts or discomfort in men
- Sleep disorders, irritability, depression
- Pain, feeling unwell, dry mouth, uncontrolled shaking, pins and needles, increased sweating
- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities
- Numbness or tingling sensation in your limbs, loss of pain sensation
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Ringing or buzzing in the ears
- Fainting, increased heart rate, chest pain, aggravation of angina may occur at the beginning of the treatment
- Low blood pressure, inflammation of the blood vessels
- Breathing difficulties, inflammation of the nasal mucosa, cough
- Dry mouth, vomiting (being sick), diarrhea, constipation, swollen gums
- Prickling and tingling sensation of the skin, itching, red patches on skin, nettle rash, hair loss, discoloration of the skin
- Muscle cramps, back pain, muscle and joint pain
- Increased need to urinate
- Impotence,
- Increase or decrease in weight

Rare (≥ 10,000)

- Confusion

Very rare (≥ 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
- 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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the CNAV (Centre National de Pharmacovigilance).

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AMLODIPINE MEDIS scored film-coated tablets

Keep out of the reach and sight of children.

Do not use your tablets after the expiry date stated on the carton or label.

Store at a temperature not exceeding 25°C.

Medicinal should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What AMLODIPINE MEDIS scored film-coated tablets contains

	Amlodipine Médís 5 mg	Amlodipine Médís 10 mg
Active substance :		
Amlodipine (as Amlodipine besylate)	5 mg (6.94 mg)	10 mg (13.88mg)
Excipients :	microcrystalline Cellulose, Dibasic calcium phosphate anhydrous, Sodium Starch glycolate, magnesium stearate	
Coating :	Opadry white : Polyvinyl alcohol, Titanium dioxide, Polyethylene glycol, macrogol, Talc	Opadry yellow: Polyvinyl alcohol, Titanium dioxide, Polyethylene glycol, macrogol, Talc, Yellow iron oxide non irradiated.

What AMLODIPINE MEDIS scored film-coated tablets look like and contents of the pack

AMLODIPINE MEDIS 5 mg is available in packs of 30 and 90 scored film-coated tablets.

AMLODIPINE MEDIS 10 mg is available in packs of 30 and 90 scored film-coated tablets.

Amlodipine Médís 5 mg	B30	9234001
	B90	9234002
Amlodipine Médís 10 mg	B30	9234003
	B90	9234004

Delivery conditions:

Table A (List I)

Marketing Authorisation Holder and Manufacturer

Les Laboratoires Médís.

Tunis road KM7 - PB 9000 - 206 Nabeul - Tunisia

Tel: (+216) 72 235 006 / Fax: (+216) 72 235 016

E-mail: contact@labomedis.com

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This is a Medicine

- A medicine is a product but not like any other product
- A medicine is a product that affects your health. If it's not used properly it can be harmful threatening.

- Strictly adhere to the prescription of your Doctor and the use instructions prescribed, follow your pharmacist advice.

- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, don't increase the doses without doctor's advice.

Keep the medicines out of reach of children

