Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Amlodipine Teva 5 mg Tablets
Amlodipine Teva 10 mg Tablets

Name and quantity of active ingredient:
Each tablet contains:
Amlodipine (as besylate) 5 mg Amlodipine (as besylate) 10 mg

Inactive ingredients and allergens: See section 2 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

- Treating hypertension.
- Treating chronic stable angina pectoris.
- Treating vasospastic angina pectoris (called Prinzmetal angina).

Therapeutic group:
Calcium channel blockers (dihydropyridines).

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine as listed in section 6, or to other calcium channel blockers. This sensitivity may be experienced as itching, reddening of the skin, or difficulty in breathing.
- You have severe low blood pressure (hypotension).
- You have a 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).
- You have heart failure after a heart attack.

Special warnings about using this medicine
Before starting treatment with Amlodipine Teva tell your doctor if you have or have ever had any of the following conditions:

- a recent heart attack.
- heart failure.
- severe increase in blood pressure (hypertensive crisis).
- liver disease.
- you are elderly and need a dose increase.

Children and adolescents
There is no information about the safety and efficacy of using this medicine in children under 6 years old. This medicine is for use in adults and in children aged 6 to 17 years old.

Other medicines and Amlodipine Teva
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Amlodipine Teva can affect other medicines and can be affected by other medicines, for example:

- simvastatin (cholesterol lowering medicine)
- itraconazole, ketoconazole (antifungal medicines)
- indinavir, nelfinavir, ritonavir (protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- Hypericum perforatum (St. John's wort)
- diltiazem, verapamil (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- cyclosporine (an immunosuppressant)
- tacrolimus, sirolimus, temsirolimus, and everolimus (that suppress the immune system after a transplantation)

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

Using this medicine and food
Do not consume grapefruit juice and grapefruit while being treated with Amlodipine Teva, because grapefruit juice and grapefruit 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 Teva.
You may take this medicine with or without meals.

Pregnancy and breastfeeding
Pregnancy
The safety of amlodipine in pregnant women has not been established yet. If you think you might be pregnant, or are planning to become pregnant, you must tell your doctor before taking this medicine.

Breastfeeding
Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or are planning to breastfeed you must tell your doctor before taking this medicine.

Driving and using machines
Amlodipine Teva may affect your ability to drive and use machines. Do not drive or use machines if the medicine makes you feel nauseous, dizzy or tired, or gives you a headache, and consult your doctor immediately.

Important information about some of this medicine's ingredients
This medicine contains less than 23 mg of sodium per tablet and is therefore considered sodium free.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
You may take this medicine with or without meals. Take this medicine at the same time each day, with a drink of water. Do not take this medicine with grapefruit juice.
Do not exceed the recommended dose!
The tablets of both doses (5 and 10 mg) may be split. There is no information about crushing/chewing the tablets.

If you have to split the tablet, we suggest you do not use a pill cutter or any other device, but that you follow the instructions below:

- Place the table on a hard flat surface (for example, a table), with the imprinted side of the tablet facing up.
- Place one of your right fingers on the right side of the score line and one of your left fingers on the left side of the score line and press at the same time to break the tablet.

If you take too much Amlodipine Teva
Taking too much of this medicine may cause your blood pressure to become low or even dangerously low. You may experience dizziness, lightheadedness, fainting or weakness. If your drop in blood pressure is severe shock can occur. Your skin could feel cool and clammy and you will lose consciousness.

Excess fluid may accumulate in your lungs (pulmonary edema), and cause shortness of breath that may develop up to 24-48 hours after intake.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Amlodipine Teva
If you forgot to take a tablet, skip the missed dose. Take your next dose at the usual time. Do not take a double dose to make up for the missed dose.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking Amlodipine Teva
Your doctor will advise you how long to take this medicine. Your medical condition may return if you stop using this medicine before you are advised to stop.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Amlodipine Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor immediately if you experience any of the following side effects after taking this medicine:

- sudden wheeziness, chest pain, difficulty in breathing or shortness of breath.
- swelling of your eyelids, face, or lips.
- swelling of the tongue and throat which causes difficulty in breathing.
- severe skin reactions including 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 any other allergic reaction.
- heart attack, changes in heart rate.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling unwell.

Very common side effect - affects more than one in ten users; If this side effect causes you problems or if it lasts for more than one week, consult your doctor: edema (fluid retention).
Common side effects - affect 1-10 in 100 users; If any of these side effects cause you problems or if they last for more than one week, consult your doctor:
headache or sleepiness or dizziness (especially at the beginning of treatment), irregular or strong heartbeat (palpitations), flushed face, abdominal pain, nausea, changes in bowel habits, diarrhea, constipation, indigestion, swollen ankles, tiredness, weakness, vision disturbances, double vision, muscle cramps.

Uncommon side effects - affect 1-10 in 1,000 users:
mood changes, anxiety, depression, difficulty sleeping, trembling, altered sense of taste, feeling faint, numbness or tingling in the limbs, loss of pain sensation, ringing in the ears, low blood pressure, sneezing or runny nose caused by inflammation of the inner lining of the nose (rhinitis), cough, dry mouth, vomiting (feeling nauseous), hair loss, increased sweating, itchy skin, skin discoloration, red patches on the skin, difficulty in passing urine, increased need to urinate at night, increased frequency of passing urine, difficulty achieving erection, breast discomfort or enlargement in men, pain, feeling unwell, muscle or joint pain, back pain, weight gain or loss.

Rare side effect - affects 1-10 in 10,000 users: confusion.
Very rare side effects - affect less than one in 10,000 users:
reduced numbers of white blood cells, reduced numbers of platelets which may result in unusual bruising or easy bleeding, excess sugar in blood (hyperglycemia), a nervous system disorder which can cause muscle weakness, tingling or numbness, swelling of the gums, bleeding 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 usually with skin rash, sensitivity to light, a disorder combining rigidity, shaking and/or movement disorders.

Side effects of unknown frequency (effects the frequency of which has not yet been determined):
trembling, rigid posture, mask-like face (few or lacking facial expressions), slow movements and a shuffling, unbalanced walk.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store below 25°C, in the original package.**

6. Additional information

In addition to the active ingredient, this medicine also contains:
Microcrystalline cellulose, calcium hydrogen phosphate anhydrous, sodium starch glycolate, magnesium stearate.

What the medicine looks like and contents of the package:
Amlodipine Teva 5 mg: round white tablet, one side is debossed A5 and with a breakline. The other side is plain.
Amlodipine Teva 10 mg: round white tablet, one side is debossed A10 and with a breakline. The other side is plain.
The package contains 20 or 30 tablets. Not all package sizes may be marketed.

Name and address of registration holder:
Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in April 2023 according to MOH guidelines

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:
Amlodipine Teva 5 mg: 138.64.31498
Amlodipine Teva 10 mg: 138.65.31499

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