

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor’s prescription only

AmloVal 5/80 mg Film-coated tablets

Active ingredients:
Each film-coated tablet contains:
Amlodipine (as besylate) 5 mg
Valsartan 80 mg

AmloVal 5/160 mg Film-coated tablets

Active ingredients:
Each film-coated tablet contains:
Amlodipine (as besylate) 5 mg
Valsartan 160 mg

AmloVal 10/160 mg Film-coated tablets

Active ingredients:
Each film-coated tablet contains:
Amlodipine (as besylate) 10 mg
Valsartan 160 mg

Inactive ingredients and allergens in the preparation: see section 6 “Additional information” and in section 2 “Important information about some of the ingredients of the medicine”.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

Treatment of essential hypertension.

AmloVal is intended for patients whose blood pressure is not properly controlled on monotherapy.

Therapeutic class:

Amlodipine – calcium channel blocker.

Valsartan – angiotensin II receptor antagonist.

AmloVal tablets contain two ingredients called amlodipine and valsartan. These two substances are intended for the treatment of high blood pressure in adults, when treatment with each ingredient separately does not provide satisfactory results.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from penetrating into the walls of the blood vessels, which prevents the blood vessels from tightening.
- Valsartan belongs to a group of substances called “angiotensin II receptor antagonists”. Angiotensin II is a substance produced by the body which causes the blood vessels to tighten, thus increasing the blood pressure. Valsartan works to block the effect of angiotensin II.

Both substances help prevent the blood vessels from tightening. As a result, the blood vessels relax and blood pressure is lowered.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to amlodipine or to any other calcium channel blockers. This may be manifested by itching, skin redness or breathing difficulties.
- You are sensitive (allergic) to valsartan or to any of the other ingredients the medicine contains (listed in section 6 “Additional information” and in section 2 “Important information about some of the ingredients of the medicine”). If you think you may be allergic, refer to the doctor before taking AmloVal.
- You have severe liver problems or biliary tract problems such as biliary cirrhosis or obstruction of biliary flow in the liver.
- You are more than three months pregnant (it is also preferable to avoid AmloVal in the beginning of pregnancy, see section “Pregnancy and breastfeeding”).
- You have severely low blood pressure (hypotension).
- You have narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- You suffer from heart failure after a heart attack.
- You have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren.

If any of these items apply to you, inform your doctor without taking AmloVal.

Special warnings regarding the use of the medicine:

Before treatment with AmloVal, tell the doctor if:

- You are sick (vomiting or diarrhea).
- You have liver or kidney problems.
- You have undergone a kidney transplant or have been diagnosed with narrowing of the kidney arteries.
- You have a problem affecting adrenal gland function, called primary hyperaldosteronism.
- You have heart failure or have had a heart attack in the past. Carefully follow the doctor’s instructions regarding the starting dose. The doctor may also check your kidney function.
- Your doctor has told you that you are suffering from narrowing of valves in the heart (aortic or mitral stenosis), or from abnormal thickening of the heart muscle (obstructive hypertrophic cardiomyopathy).
- You have ever had swelling, particularly of the face and throat, while taking other medicines (including ACE inhibitors). If you experience these symptoms, **stop taking AmloVal and refer to your doctor immediately. In this case, never take AmloVal again.**
- If you experience abdominal pain, nausea, vomiting or diarrhea after taking AmloVal, your doctor will decide on further treatment. Do not stop taking Amloval on your own.
- You are taking any of the medicines used to treat high blood pressure:
 - ACE inhibitors (e.g., enalapril, lisinopril, ramipril), in particular if you suffer from diabetes-related kidney problems.
 - Aliskiren.

Children and adolescents:

AmloVal is not recommended for children and adolescents under the age of 18 years.

Tests and follow-up:

Your doctor may regularly check your kidney function, blood pressure and the amount of electrolytes (e.g., potassium) in your blood.

See additional information in the section “**Do not use this medicine if**”.

If any of the items apply to you, inform the doctor before taking AmloVal.

Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Your doctor may need to change the dosage or take other precautionary measures. In certain cases, you may need to stop taking one of the medicines.

Especially inform the doctor or pharmacist if you are taking medicines from the following groups:

- ACE inhibitors or aliskiren (see information in sections “**Do not use this medicine if**” and “**Special warnings regarding the use of the medicine**”).
- Diuretics (a type of medicine that increases urination).
- Lithium, a medicine used to treat certain types of depression.
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other substances that may increase potassium levels.
- Certain types of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase 2 (Cox-2) inhibitors. The doctor may also check your kidney function.
- Medicines for the treatment of seizures (such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone).
- A herbal extract for calming – Hypericum perforatum (St. John’s wort).
- Nitroglycerin and other nitrates or other medicines belonging to the vasodilators group.
- Medicines to treat HIV/AIDS (such as ritonavir, indinavir, nelfinavir).
- Medicines used to treat fungal infections (such as ketoconazole, itraconazole).
- Medicines used for treatment of bacterial infections (such as rifampicin, erythromycin, clarithromycin, telithromycin).
- Verapamil, diltiazem (medicines for the heart).
- Simvastatin (a medicine used for lowering cholesterol levels).
- Dantrolene (infusion for abnormal body temperatures).
- Tacrolimus (used to prevent transplant rejection by your immune system).
- Medicines used to protect against transplant rejection (cyclosporine).

Use of the medicine and food:

Do not consume grapefruit and grapefruit juice while taking AmloVal. This is because grapefruit and grapefruit juice may increase the levels of the active ingredient amlodipine in the blood, which may unexpectedly increase the blood pressure lowering effect. AmloVal may be taken with or without food.

Pregnancy and breastfeeding:

Pregnancy

You should tell your doctor if you think you are pregnant or if you might become pregnant. Your doctor will generally recommend you to stop taking AmloVal before becoming pregnant or immediately when you find out that you are pregnant and will recommend that you take another medicine instead of AmloVal. AmloVal is not recommended in the beginning of pregnancy (in the first three months of pregnancy) and **must not** be taken if you are more than three months pregnant, as it may cause serious harm to the fetus if used after the third month of pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or are planning to start breastfeeding. Small amounts of amlodipine pass into breastmilk. It is not recommended to take AmloVal during breastfeeding and your doctor may recommend another treatment for you if you wish to breastfeed, especially if the baby was just born or born prematurely.

Consult the doctor or pharmacist before using any medicine.

Driving and operating machinery:

This medicine may cause dizziness. This can affect your ability to concentrate. Therefore, if you do not know how this medicine will affect you, do not drive, do no operate machinery and do not perform other activities that require concentration.

Important information about some of the ingredients of the medicine:

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is thus considered to be “sodium-free”.

3. How should you use the medicine?

Always use the medicine according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

This will help to achieve the best results and reduce the risk of side effects.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is one tablet per day:

- It is preferable to take the medicine at the same time each day.
- Swallow the tablets with a glass of water.

- AmloVal may be taken with or without food. Do not take AmloVal with grapefruit or grapefruit juice.
- There is no information regarding pulverizing, halving or chewing the tablets.

Depending on your response to the treatment, the doctor may suggest a higher or lower dosage.

Do not exceed the recommended dose.

AmloVal in the elderly (aged 65 and above)

Your doctor will exercise caution when increasing the dosage. If you have further questions about using the medicine, ask your doctor or pharmacist.

If you accidentally took a higher dosage

If you took an overdose or if a child accidentally swallowed this medicine, refer immediately to a doctor or to a hospital emergency room and take the package of the medicine with you. Excess fluid may accumulate in your lungs (pulmonary edema), causing shortness of breath which may develop up to 24-48 hours after taking it.

If you forgot to take the medicine

If you forgot to take the medicine at the designated time, take a dose as soon as you remember. Afterwards, take the next dose at the usual time. However, if it is almost time to take the next dose, do not take the forgotten dose. Do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult a doctor.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Stopping treatment with AmloVal may cause worsening of your illness. Do not stop taking the medicine, unless the doctor instructs you to.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using AmloVal may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

There are serious side effects that require immediate medical treatment:

Few patients have experienced these serious side effects.

If any of the following effects occur, refer to a doctor immediately:

Rare side effects – effects that occur in 1-10 users out of 10,000:

An allergic reaction with symptoms such as rash, itching, swelling of the face or lips or tongue, breathing difficulties, low blood pressure (feeling faint, light-headedness).

Very rare side effects – effects that occur in less than one user out of 10,000:

Intestinal angioedema: swelling in the bowel that occurs with symptoms like abdominal pain, nausea, vomiting and diarrhea.

Other side effects that may occur with AmloVal:

Common side effects – effects that occur in 1-10 users out of 100:

Flu; stuffy nose, sore throat and discomfort when swallowing; headache; swelling of the arms, palms of the hands, legs, ankles or feet; tiredness; weakness; redness and feeling of warmth in the face and/or neck.

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

Dizziness; nausea and abdominal pain; dry mouth; drowsiness; tingling or numbness in the hands or feet; vertigo; fast heartbeat including palpitations; dizziness upon standing up; cough; diarrhea; constipation; skin rash; redness of the skin; swelling in the joints, back pain; pain in joints.

Rare side effects – effects that occur in 1-10 users out of 10,000:

Anxiety; ringing in the ears; fainting; passing more urine than usual or feeling an increased urge to urinate; inability to obtain or maintain an erection; sensation of heaviness; low blood pressure with symptoms such as dizziness, mild light-headedness; increased sweating; skin rash all over the body; itching; muscle spasms.

If the effects mentioned above affect you severely, refer to your doctor.

Side effects reported upon use of amlodipine or valsartan when taken separately, which do not occur when using AmloVal or occur more frequently than with AmloVal:

Amlodipine

Refer to the doctor immediately if you feel any of the following very rare and serious side effects after taking the medicine:

- Sudden wheezing while breathing, chest pain, shortness of breath or difficulty in breathing.
- Swelling of the eyelids, face or lips.
- Swelling of the tongue and throat causing great difficulty in breathing.
- Severe skin reactions including intense skin rash, hives, redness of the skin all over the body, intense itching, blistering, peeling and swelling of the skin, inflammation of the mucous membrane (Stevens-Johnson syndrome, toxic epidermal necrolysis), or other allergic reactions.
- Myocardial infarction, irregular heart rate.
- Inflammation of the pancreas which may cause severe abdominal and back pain accompanied by a general feeling of being unwell.

The following side effects have been reported. If the following effects cause you problems or if they last more than one week, refer to your doctor:

Common side effects – effects that occur in 1-10 users out of 100:

Dizziness, sleepiness, palpitations (awareness of heartbeats), flushing, swelling of the ankles (edema), abdominal pain, nausea.

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

Mood swings, anxiety, depression, insomnia, trembling, changes in the sense of taste, fainting, loss of pain sensation, visual disturbances, visual impairment, ringing in the ears, low blood pressure, sneezing/runny nose caused by inflammation of the nasal tissue (rhinitis), indigestion, vomiting, hair loss, increased sweating, itchy skin, skin discoloration, urination disorder, increased need to urinate at night, more frequent urination, inability to obtain an erection, discomfort or enlargement of the breasts in men, pain, feeling unwell, muscle pain, muscle cramps, weight gain or loss.

Rare side effects – effects that occur in 1-10 users out of 10,000:

Confusion

Very rare side effects – effects that occur in less than one user out of 10,000:

A decrease in the number of white blood cells, a decrease in the number of blood platelets, which may cause unusual bruising or easy bleeding (red blood cell damage), excess of sugar in the blood (hyperglycemia), swelling of the gums, abdominal bloating (gastritis), abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), increased liver enzymes, which may affect certain medical tests, increased muscle tension (tone), inflammation of blood vessels occasionally accompanied by skin rash, sensitivity to light, disorders combining rigidity, tremor and/or movement difficulties.

Valsartan

Side effects with unknown frequency (effects whose frequency has not yet been determined):

A decrease in red blood cells, fever, sore throat or mouth sores due to infections; spontaneous bleeding or bruising; high levels of potassium in the blood; abnormal liver test results; decreased renal function or a severe reduction in renal function; swelling mainly of the face and throat; muscle pain; rash, purplish-red spots, fever, itching; allergic reactions; skin blisters (symptoms of a condition called dermatitis bullous).

If you feel these effects, refer to your doctor immediately!

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not use if the package is damaged.

6. Additional information

In addition to the active ingredients, the medicine also contains:

AmloVal film-coated tablets 5/80 mg, 5/160 mg, 10/160 mg:

Cellulose, microcrystalline; sodium starch glycolate (type-A); starch, pregelatinised (maize starch); povidone (K-30); silica, colloidal anhydrous; magnesium stearate

AmloVal film-coated tablets 5/80 mg, 5/160 mg – composition of the coating:

Hypromellose 2910; talc; macrogol 4000; titanium dioxide; iron oxide yellow

AmloVal film-coated tablets 10/160 mg – composition of the coating:

Hypromellose 2910; titanium dioxide; macrogol 4000; talc; iron oxide yellow; iron oxide red

What does the medicine look like and what are the contents of the package?

AmloVal 5/80 mg: yellow colored, round shaped, beveled edge, biconvex film-coated tablet, debossed with “J” on one side and “79” on the other side.

AmloVal 5/160 mg: yellow colored, ovaloid shaped, beveled edge, biconvex film-coated tablet, debossed with “J” on one side and “37” on the other side.

AmloVal 10/160 mg: light yellow colored, ovaloid shaped, beveled edge, biconvex film-coated tablet, debossed with “J” on one side and “38” on the other side.

Package type: the tablets are packed in trays/blisters which are packed in carton boxes.

Package sizes: 28 or 30 tablets. The number of tablets in each package appears on the carton package.

Not all package sizes may be marketed.

Manufacturer: Aurobindo Pharma Ltd., India.

License holder and importer: Inovamed Ltd., P.O. Box 62, Even Yehuda.

Revised in November 2025.

Registration numbers of the medicines in the national drug registry of the Ministry of Health:

AmloVal 5/80 mg: 179-78-37748

AmloVal 5/160 mg: 179-79-37749

AmloVal 10/160 mg: 179-80-37750