

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with
a doctor's prescription only.

Amlow 5, 10 Tablets

Composition:

Each **Amlow 5** tablet contains:

Amlodipine maleate equivalent to 5 mg of Amlodipine.

Each **Amlow 10** tablet contains:

Amlodipine maleate equivalent to 10 mg of Amlodipine.

A list of inactive and allergenic ingredients in the preparation, see section 6: "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

The medicine is intended for adults, children and adolescents of ages 6-17.

The medicine is not intended for children under the age of 6.

1. WHAT IS THE MEDICINE INTENDED FOR?

- For treatment of hypertension.
- For treatment of chronic stable angina pectoris.
- For treatment of vasospastic angina (Prinzmetal's angina).

Therapeutic group: Calcium channel blockers (dihydropyridines).

2. BEFORE USING THE MEDICINE

⚠ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, or to any of the additional ingredients contained in the medicine or to other medicines from the dihydropyridine family
- You are suffering from severe hypotension
- You are suffering from narrowing of the aortic heart valve (aortic stenosis)
- You are suffering from shock, including cardiogenic shock
- You are suffering from heart failure after a cardiac event

Special warnings regarding use of the medicine

Do not use the medicine without consulting the doctor before starting treatment:

- If you are suffering, or have suffered in the past, from impaired function of the heart and/or blood vessels.
- If you are suffering, or have suffered in the past, from a severe increase in blood pressure.
- If you are suffering, or have suffered in the past, from impaired liver function.
- If you are elderly and the dosage needs to be increased.

! If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

! During the course of treatment with this medicine, blood pressure, heart rate and ECG tests should be performed.

! There is no information regarding children under the age of 6. Use of this medicine is for adults and/or children and adolescents from the age of 6 to 17.

! This medicine may lower blood pressure even more if you are already taking other antihypertensives.

⚠ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Cholesterol-lowering medicines from the statin group - since the combination raises the level of statins in the blood
- Itraconazole, ketoconazole (to treat fungus), indinavir, nelfinavir, ritonavir (to treat AIDS) antibiotics (e.g., erythromycin, clarithromycin), other antihypertensives (e.g., diltiazem, verapamil) - since the combination raises the level of **Amlow** in the blood
- Rifampicin, Hypericum (St. John's wort) - since the combination lowers the level of **Amlow** in the blood
- Dantrolene (smooth muscle relaxant)
- Medicines that affect the central nervous system (such as medicines for sedation, for sleep, Parkinson's disease, epilepsy)
- Nonsteroidal anti-inflammatory drugs
- Medicines for erectile disorders (e.g., Viagra)
- Lithium
- Estrogens
- Anticoagulants (e.g., warfarin)
- Cyclosporin (an immunosuppressant)
- Tacrolimus (a medicine that suppresses the immune system after transplantation)

⚠ Use of the medicine and food:

The medicine can be used with or without food. Swallow the medicine with a bit of water.

During the course of treatment with the medicine, do not eat grapefruits or drink grapefruit juice - since the combination raises the level of **Amlow** in the blood.

⚠ Pregnancy and breastfeeding:

The effect of the medicine and its safety have not been tested in pregnant women.

It is unknown whether the medicine passes into breast milk during breastfeeding.

Before taking the medicine, consult the doctor if you are in the first/last trimester of pregnancy, are planning a pregnancy, are breastfeeding or are planning to breastfeed.

⚠ Driving and operating machinery:

Amlow may affect the ability to drive and to operate machinery. If the medicine causes you to feel unwell, dizzy, tired or to have a headache, avoid driving or operating machinery and consult a doctor immediately.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions!

The dosage and treatment regimen will be determined by the doctor only.

The dosage will be individually adjusted for each patient by the attending doctor, by gradual dose increases.

Use this medicine at set intervals, as determined by the attending doctor. Complete the treatment recommended by the doctor.

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

Do not exceed the recommended dose.

If necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing the tablet.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, skip the forgotten dose and take the next dose at the scheduled time, but never take a double dose!

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Amlow** may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment and refer to a doctor immediately if the following side effects occur:

- Sudden wheezing, chest pain, breathing difficulties, shortness of breath.
- Swelling of the eyelids, face, lips, tongue or throat that can cause breathing difficulties.
- Hives, redness of the skin all over the body, itching, rash.
- Blistering of the skin, peeling or swelling of the skin, inflammation of mucous membranes (Stevens-Johnson syndrome), or any other allergic reaction.
- Heart attack, changes in heart rate.
- Inflammation of the pancreas, which can cause back and abdominal pain accompanied by an unwell feeling.

Very common side effects – occur in more than one user in ten:

- Edema (accumulation of fluids).

If they are a problem for you or continue for over a week, contact the doctor.

Common side effects – effects that occur in up to 1 in 10 users:

- Headache, tiredness or dizziness (especially at the beginning of treatment).
- Palpitations, facial flushing.
- Abdominal pain, nausea.
- Ankle swelling.
- Sleepiness, weakness.
- Altered bowel habits, diarrhea, constipation, indigestion.
- Vision disturbances, double vision.
- Muscle cramps.

If you suffer from one of these effects or if the effects last for more than one week, refer to a doctor.

Uncommon side effects – effects that occur in up to 1 in 100 users:

- Mood changes, anxiety, depression, sleeping difficulties.
- Trembling.
- Changes in sense of taste.
- Feeling faint.
- A sensation of paralysis in the limbs, tingling sensation 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.

- Hair loss.
- Increased sweating.
- Itchy skin, skin discoloration, red patches on skin.
- Difficulty in passing urine, increased need to urinate at night, increased frequency of passing urine.
- Erection problems.
- Discomfort or enlargement of the breasts in men.
- Pain, feeling unwell.
- Muscle pain, joint pain, back pain.
- Weight gain or loss.

Rare side effects – effects that occur in up to 1 in 1,000 users:

- Confusion.

Very rare side effects – effects that occur in up to 1 in 10,000 users:

- Decreased number of white blood cells, decreased number of platelets (may result in bruising or bleeding easily).
- Increased blood sugar level.
- Nervous system disturbance that may cause: weakness, tingling or numbness.
- Swelling of the gums.
- Abdominal bloating (gastritis).
- Improper functioning of the liver: inflammation of the liver (hepatitis), yellowish skin (jaundice), increase in liver enzymes in the blood.
- Increase in muscle tone.
- Inflammation of blood vessels, usually accompanied by skin rash.
- Sensitivity to light.
- Disorder accompanied by rigidity, tremor, and/or movement difficulty.
- Yellowing of the eyes.
- Hypotension
- Heartburn

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

If these effects last and are bothersome, refer to a doctor!

Additional side effects in children:

In addition to the listed side effects, children may also suffer from nosebleeds.

Parents should report to the attending doctor of any side effect as well as any additional medicine being given to the child.

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

Side effects can be reported to the Ministry of Health by clicking on the link "[Report side effects of drug treatment](#)" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects.

Alternatively, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store at a temperature below 25°C, and in a place protected from light.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, Sodium starch glycolate, Stearic acid, Colloidal silicon dioxide.

What the medicine looks like and the contents of the package:

Amlow is packaged in trays (blister) inserted into a carton package. Each package contains 10, 20, 30 or 1,000 tablets. Not all package sizes may be marketed.

Amlow 5 and **Amlow 10** are round, biconvex, white tablets with a score line on one side.

Registration holder: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

This leaflet was checked and approved by the Ministry of Health in: June 2015 and was updated in accordance with the Ministry of Health guidelines in June 2018.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Amlow 5: 131 65 31034 01

Amlow 10: 131 66 31035 01