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.

For a list of inactive and allergenic ingredients in the preparation: see chapter 2, section "Important information about some of the ingredients of the medicine" and chapter 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.

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 as detailed in chapter 6, or to other calcium channel blockers. This can manifest by itching, redness or breathing difficulty.
- 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 regarding use of the medicine

Before treatment with Amlow, 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 the dosage needs to be increased.

Children and adolescents:

There is no information regarding the safety and effectiveness 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.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Amlow can affect other medicines and can be affected by other medicines, for example:

- Itraconazole, ketoconazole (antifungals).
- Indinavir, nelfinavir, ritonavir (called protease inhibitors, to treat HIV).
- 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 (medicines used to alter the way your immune system works).
- Simvastatin (cholesterol-lowering medicine).
- Cyclosporin (an immunosuppressant).

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

Use of the medicine and food:

Do not consume grapefruit or grapefruit juice while you are being treated with **Amlow**, since grapefruit juice and grapefruit can lead to an increase in the blood level of the active ingredient amlodipine, which may cause an unpredictable increase in the blood pressure-lowering effect of **Amlow**.

The medicine can be taken regardless of meals.

Pregnancy, breastfeeding and fertility

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 using **Amlow**.

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 using **Amlow**.

Driving and operating machinery:

Amlow may affect the ability to drive and to operate machinery. If the medicine causes you to feel nauseous, dizzy, tired or to have a headache, do not drive or operate machinery and consult a doctor immediately.

Important information about some of the ingredients of the medicine:

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the physician or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

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

You may take this medicine with or without meals. Take this medicine at the same time each day, with water. Do not take **Amlow** with grapefruit juice.

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 take too much Amlow

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may experience lightheadedness, dizziness, 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 oedema), and cause shortness of breath that may develop up to 24-48 hours after intake.

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 forget to take Amlow

If you forgot to take a tablet at the designated time, 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 regimen as recommended by the doctor.

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

If you stop taking Amlow

Your doctor will advise you how long to take this medicine. Your medical problem may return if you stop using the medicine before you are advised to stop.

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.

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

- Sudden wheezing, chest pain, breathing difficulties or shortness of breath.
- Swelling of the eyelids, face or lips.
- Swelling of the tongue and throat that can cause breathing difficulties.
- Severe skin reactions including skin rash, hives, redness of the skin all over the body, severe itching, blistering of the skin, 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 can cause severe back and abdominal pain accompanied by an unwell feeling.

Additional side effects:

Very common side effects – effects that occur in more than one user in ten: (If they are a problem for you or continue for over a week, contact your doctor).

- Edema (accumulation of fluids).

Common side effects – effects that occur in 1-10 in 100 users: (If they are a problem for you or continue for over a week, contact your doctor).

- Headache, dizziness, or sleepiness (especially at the beginning of treatment).
- Irregular or strong heartbeat (palpitations), facial flushing.
- Abdominal pain, nausea.
- Altered bowel habits, diarrhea, constipation, indigestion.
- Tiredness, weakness.
- Vision disturbances, double vision.
- Muscle cramps.
- Ankle swelling.

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

- Mood changes, anxiety, depression, sleeping difficulties.
- Trembling, changes in 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 skin.
- Disturbance in passing urine, increased need to urinate at night, increased frequency of passing urine.
- Difficulty obtaining an erection, 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 1-10 in 10,000 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 which may result in unusual bruising or bleeding easily.
- Increased blood sugar level (hyperglycemia).
- Nervous system disturbance that may cause: muscle weakness, tingling or numbness.
- Swelling of the gums.
- Abdominal bloating (gastritis).
- Improper functioning of the liver: inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase in the blood, which may have an effect on some medical tests.
- Increase in muscle tone.
- Inflammation of blood vessels, usually accompanied by skin rash.
- Sensitivity to light.
- Disorders combining rigidity, tremor, and/or movement disorders.

Side effects of unknown frequency (effects whose frequency has not been established yet):

- Trembling, rigid posture, mask-like face (few or lack of facial expressions), slow movements and a shuffling, unbalanced walk.

Reporting side effects

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.

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, or by entering the link:

http://sideeffects.health.gov.il

Additionally, 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 and sight 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 and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

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

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

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