

AMLIBON TABLET

Amlodipine besilate (5mg, 10mg)

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WHAT AMLIBON IS USED FOR

Amlodipine belongs to a group of medicines called calcium channel blockers.

Amlodipine is used to treat:

- high blood pressure (hypertension)
- a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina.

HOW AMLIBON WORKS

In patients with high blood pressure, your medicine works by relaxing blood vessels, so that blood passes through them more easily.

In patients with angina, Amlodipine works by improving blood supply to the heart muscle, which then receives more oxygen, and as a result chest pain is prevented. Amlodipine does not provide immediate relief of chest pain from angina.

BEFORE YOU TAKE AMLIBON

- When you must not use it

Do NOT take Amlibon

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of your medicine listed in "PRODUCT DESCRIPTION section", or to any other calcium antagonists. The symptoms include itching, reddening of the skin or difficulty in

breathing.

- if you have severe low blood pressure (hypotension)
- if you have 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)
- If you suffer from heart failure after a heart attack

- Before you start to use it

You should inform your doctor if you have or have had any of the following conditions:

- recent heart attack
- heart failure
- severe increase in blood pressure (hypertensive crisis)
- liver disease
- you are elderly

Pregnancy and breast-feeding

Pregnancy

The safety of amlodipine 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.

Breast-feeding

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Amlodipine.

Children and adolescents (under 18 years of age)

The use of amlodipine is not recommended in children and adolescents (below 18 years of age) due to insufficient data on safety and efficacy.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained

without a prescription.

Amlodipine may affect or be affected by other medicines, such as:

- ketoconazole, itraconazole (antifungal medicines)
- Ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- *Hypericum perforatum* (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- simvastatin (used to lower elevated cholesterol levels in blood)

- Taking with food and drinks

Grapefruit juice and grapefruit should not be consumed by people who are taking Amlodipine. This is because grapefruit and grapefruit juice 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.

HOW TO TAKE AMLIBON

- How much to use

Always take Amlodipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual initial dose is Amlodipine 5 mg once daily. The dose can be increased to maximum Amlodipine 10 mg once daily.

- When to use it

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. Do not take Amlodipine with grapefruit juice.

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- How long to use it

Your doctor will advise you how long to take Amlodipine. Your condition may return if you stop using your medicine before you are advised.

If you have any further questions the use of this product, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take AMLIBON

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 missed dose.

- If you use too much (overdose)

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Amlodipine tablets.

WHILE YOU ARE USING IT

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking AMLIBON.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give AMLIBON to anyone else, even if they have the same symptoms or condition as you.

Do not stop taking the medicine

unless advised by your doctor.

- Things to be careful of

Driving and using machines

Amlodipine may affect your ability to drive or use machines.

If the tablets make feel you sick dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

SIDE EFFECTS

Like all medicines, Amlodipine can cause side effects, although not everybody gets them.

Visit your doctor immediately if experience any of the following very rare, severe side effects after taking this medicine.

- 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) 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 common side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your doctor.

Common: affects 1 to 10 users in 100

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Flushing

- Abdominal pain, feeling sick (nausea)
- Anke swelling (oedema), tiredness

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: affects 1 to 10 users in 1,000

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Numbness or tingling sensation in your limbs; loss of pain sensation
- Visual disturbances, double vision, ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- Altered bowel habits, diarrhoea, constipation, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection; discomfort or enlargement of the breasts in men
- Weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain
- Weight increase or decrease

Rare: affects 1 to 10 users in 10,000

- Confusion

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Very rare: affects less than 1 user in 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
- Cough, 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the **National Centre for Adverse Drug Reaction Monitoring** by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

STORAGE AND DISPOSAL OF AMLIBON

- Storage

Keep out of the reach and sight of children.

Do not use Amlodipine after the expiry date "EXP" which is stated on the packaging. The expiry date refers

to the last day of that month. Blister: Keep the blister in the outer carton in order to protect from light. Tablet container: Store in the original package in order to protect from light. Storage below temperature 25°C.

- Disposal

Medicines 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.

PRODUCT DESCRIPTION

AMLIBON 5 mg tablet

- What it looks like

A white or almost white, oblong tablet with bevelled edges, score line on one side and marked with a "5" on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. When the tablet has been divided, one part should be taken straight after the other.

- Ingredients

Active Ingredients

The active substance is amlodipine. Each tablet contains 5 mg of amlodipine (as besilate).

Inactive ingredients

The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (type A) and magnesium stearate.

AMLIBON 10 mg tablets

- What it looks like

A white or almost white, oblong tablet with bevelled edges, score line on one side and marked with a "10" on the other side.

The tablet can be divided into equal halves.

- Ingredients

Active Ingredients

The active substance is amlodipine. Each tablet contains 10 mg of amlodipine (as besilate).

Inactive ingredients

The other ingredients are microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate (type A) and magnesium stearate.

MAL NO.

Amlibon 5mg- MAL10053657AZ

Amlibon 10mg- MAL10053658AZ

MANUFACTURER

Lek Pharmaceuticals d.d

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Slovenia

PRODUCT REGISTRATION HOLDER

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