



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

- What Amlozaar is and what it is used for
- What you need to know before you take Amlozaar
- How to take Amlozaar
- Possible Side Effects
- How to store Amlozaar
- Contents of the pack and other information

1. What Amlozaar is and what it is used for

Losartan & Amlodipine tablets are a combination of an angiotensin II receptor antagonist (losartan) and calcium antagonists (Amlodipine). Losartan & Amlodipine tablets are indicated for the treatment of indicated for the treatment of mild to moderate hypertension. It is also indicated in hypertension not responding to monotherapy with calcium antagonists or angiotensin II receptor antagonists. It may also be substituted for the titrated doses of the individual components.

2. What you need to know before you take Amlozaar

Contact your doctor if you are not sure if you belong to a patient group described below.

Do not take Amlozaar

- If you are allergic (hypersensitive) to losartan, Amlodipine or to any of the other ingredients of Losartan & Amlodipine Tablets.
- You have a narrowing of the aortic heart valve (aortic stenosis), unstable angina pectoris or cardiogenic shock.
- You are pregnant or breast feeding.

Please ask your doctor about the conditions mentioned above. You should also ask if you have previously had any of these conditions.

Talk to your doctor before taking Amlozaar

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

- Recent heart attack (within the last month)
- Severe increase in blood pressure (hypersensitive crisis)
- Liver disease.
- If you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue).
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys)
- or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body
- If you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently,
- If your liver function is impaired.
- If you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a β -blocker concomitantly,
- If you have problems with your heart valves or heart muscle,
- If you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).

Children and adolescents

Losartan has been studied in children. For more information, talk to your doctor.

Losartan Tablets are not recommended for use in children suffering from kidney or liver problems, or children under 6 years old, as limited data are available in these patient groups.

Safety and effectiveness have been studied in 6-17 year old boys and in girls. Amlodipine Tablets have not been studied in children under the age of 6 years. For more information, talk to your doctor.

Other medicines and Amlozaar

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines and natural products.

Take particular care if you are taking the following medicines while under treatment with Losartan Tablets:

- Other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofene, amifostine,
- Medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamteren, spironolactone] or heparine),

- Non-steroidal anti-inflammatory drugs such as indomethacin, including cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan.
- ACE (angiotensin-converting enzyme) inhibitors (for the treatment of blood pressure, certain heart conditions, kidney disease in patients with diabetes)- Concomitant treatment should be limited to individually defined cases with close monitoring of renal function.

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function. Lithium containing medicines should not be taken in combination with losartan without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

Pregnancy and breast-feeding

If you think you might be pregnant, or are planning to get pregnant, tell your doctor before you take Losartan & Amlodipine Tablets.

You should not take Losartan & Amlodipine Tablets if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

Losartan Tablets are unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people.

If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Amlodipine Tablets is unlikely to affect your ability to drive or use machines.

3. How to take Amlozaar

Always take Losartan & Amlodipine tablets exactly as your doctor has instructed you. Your doctor will decide on the appropriate dose of Losartan & Amlodipine tablets depending on your condition and whether you are taking other medicines.

How much to take

The usual initial dosage is one tablet daily. If blood pressure control is inadequate after a week or two, the dose may be increased to two tablets daily. The dosage, however, should be individualized.

How long to take it

It is important to continue taking Losartan & Amlodipine tablets for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you take more Amlozaar, than you should (overdose)

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. An overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Amlozaar

Try to take Amlodipine & Losartan tablets daily as prescribed. However, if you miss a dose, do not take an extra dose.

Just resume your usual schedule.

If you stop taking Amlozaar

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

If you have any further questions on how to take this product, ask your doctor or pharmacist.

4. Possible side effects

Losartan

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

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing). This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The following side effects have been reported with losartan:

Common (may affect up to 1 in 10 people):

- Dizziness,
- Vertigo,
- Debility,
- Fatigue,
- Too little sugar in the blood (hypoglycaemia),
- Too much potassium in the blood (hyperkalaemia),
- Changes in kidney function including kidney failure,
- reduced number of red blood cells (anaemia),
- Increase in blood urea, serum creatinine and serum potassium in patients with heart failure,
- Fall in blood pressure, including a dose-related orthostatic effect, appearing when rising from lying or sitting position. It may cause dizziness, light headedness or fainting (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics).

Uncommon (may affect up to 1 in 100 people):

- Somnolence,
- Headache,
- sleep disorders,

- Feeling of increased heart rate (palpitations),
- Severe chest pain (angina pectoris),
- Shortness of breath (Dyspnoea),
- Abdominal pain,
- Severe constipation,
- Diarrhoea,
- Nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- Rash.
- localized swelling (oedema),
- cough.

Rare (may affect up to 1 per 1,000 people):

- Hypersensitivity reactions,
- Angiooedema,
- Inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura),
- Numbness or tingling sensation (paraesthesia).
- Fainting (syncope),
- Very rapid and irregular heartbeat (atrial fibrillation).
- Brain attack (stroke).
- Inflammation of the liver (hepatitis).
- Elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

Not known (frequency cannot be estimated from the available data):

- reduced number of thrombocytes.
 - Migraine.
 - Liver function abnormalities.
 - Muscle pain,
 - Joint pain,
 - Flu-like symptoms,
 - back pain,
 - Urinary tract infection,
 - increased sensitivity to the sun (photosensitivity),
 - Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis),
 - Impotence,
 - Inflammation of the pancreas (pancreatitis),
 - Low levels of sodium in the blood (hyponatraemia).
 - Depression,
 - Generally feeling unwell (malaise),
 - ringing, buzzing, roaring, or clicking in the ears (tinnitus).
- Distorted sense of taste (dysgeusia).

Side effects in children are similar to those in adults.

Amlodipine

Like all medicines, Amlodipine Tablets can cause side effects, although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

Although they are very rare, the symptoms can be severe.

- Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

The following Common side-effects have been reported. If any of these cause problems or if they last more than a week, you should contact your doctor.

Common side effects

- Headache, dizziness, sleepiness
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle 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 side effects

- Mood changes, sleeplessness
- Trembling, taste abnormalities, fainting, weakness
- Visual disturbances, ringing in the ears
- Low blood pressure
- Shortness of breath, sneezing/running nose
- Altered bowel habit, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin
- Increased need to urinate especially at night, inability to obtain an erection
- Chest pain, weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain
- Weight increase or decrease
- Enlargening of male breasts

Very rare side effects reported

- Unusual bruising and bleeding (red blood cell damage)
- Severe skin reaction
- Excess sugar in blood (diabetes)
- Increased sensitivity of the skin, pins and needles, loss of pain sensation
- Heart attack
- Hives
- Abdominal bloating (gastritis)
- Cough

- Inflamed pancreas
- Abnormal liver function, inflammation of the liver, yellowing of the skin (jaundice), liver enzyme increases.

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.

5. How to store Amlozaar

Store below 30°C. Keep away from the reach of children

Do not use this medicine after the expiry date which is stated on the packaging after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Amlozaar contains

Active ingredients: Losartan Potassium and Amlodipine

In active ingredients: Microcrystalline Cellulose, Sodium Starch Glycollate, Colloidal Anhydrous Silica, Dibasic Calcium Phosphate, Sodium Bicarbonate, Talc, Magnesium Stearate, Hypromellose, Titanium Dioxide, Propylene Glycol, Quinolone Yellow Lake

What Amlozaar looks like and contents of the pack

Light Yellow coloured, circular biconvex film-coated tablets plain on both sides

10 Tablets are packed in Alu/Alu Blister

Manufacturer

MICRO LABS LIMITED

92, SIPCOT,

HOSUR-635 126, INDIA

Marketing Authorisation Holder

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INDIA

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