

Package leaflet: Information for the patient

Losanet AM 100 mg/5 mg Tablets Losanet AM 100 mg/10 mg Tablets

Losartan potassium/amlodipine (as amlodipine besylate)

Read all of this leaflet carefully before you start taking 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, consult 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, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1. What Losanet AM is and what it is used for

Losanet AM tablets contain two substances called losartan potassium and amlodipine. Both of these substances help to control high blood pressure.

- Losartan potassium belongs to a group of substances called “angiotensin II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Losartan potassium works by blocking the effect of angiotensin II.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Losanet AM is used to treat high blood pressure in patients receiving losartan potassium and amlodipine from separate tablets/capsules containing the same component doses and in adults whose blood pressure is not controlled enough with either amlodipine or losartan potassium monotherapy.

2. What you need to know before you take Losanet AM

Do not take Losanet AM

- If you are allergic to amlodipine or to any other calcium channel blockers. This may involve itching, reddening of the skin or difficulty in breathing.
- If you are allergic to losartan potassium or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver problems or bile problems such as biliary cirrhosis or cholestasis.
- If you have severe kidney problems or if you are undergoing dialysis.
- If you are, for more than 3 months, pregnant. (It is also better to avoid Losanet AM in early pregnancy, see Pregnancy section).
- If you have severe low blood pressure (hypotension).
- If 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).
- If you suffer from heart failure after a heart attack.

If any of the above applies to you, do not take Losanet AM and consult your doctor.

Warnings and precautions

Consult your doctor or pharmacist before taking this medicine.

Take special care with Losanet AM:

- If you have been sick (vomiting or diarrhoea).
- If you have liver or kidney problems.
- If you have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- If you have a condition affecting the renal glands called “primary hyperaldosteronism”.
- If you have had heart failure or have experienced a heart attack. Follow your doctor’s instructions for the starting dose carefully. Your doctor may also check your kidney function.
- If your doctor has told you that you have a narrowing of the valves in your heart (called “aortic or mitral stenosis”) or that the thickness of your heart muscle is abnormally increased (called “obstructive hypertrophic cardiomyopathy”).
- If any of the above applies to you, consult your doctor.
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking Losanet AM and contact your doctor straight away. You should never take Losanet AM again.
- If you are taking any of the following medicines used to treat high blood pressure:
 - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren

Other medicines and Losanet AM

Please consult your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment can be influenced if Losanet AM is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:

- Diuretics (a type of medicine also called “water tablets” which increases the amount of urine you produce)
- Lithium (a medicine used to treat some types of depression)
- Potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels
- Certain types of painkillers called Non-Steroidal Anti-Inflammatory medicines (NSAIDs) or selective Cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function
- Anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone),
- St. John’s wort
- Nitroglycerin and other nitrates, or other substances called “vasodilators”
- Medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir)
- Medicines used to treat fungal infections (e.g. itraconazole, ketoconazole)
- Verapamil, diltiazem (used in the treatment of hypertension, angina pectoris and some types of arrhythmia).
- Medicines used to treat bacterial infections (such as rifampicin, erythromycin, clarithromycin, talithromycin);
- Simvastatin (a medicine used to control high cholesterol levels);
- Dantrolene (infusion for severe body temperature abnormalities);
- Medicines used to protect against transplant rejection (ciclosporin).

Losanet AM with food and drink

You can take Losanet AM with or without food. Grapefruit and grapefruit juice should not be consumed by people who are taking Losanet AM. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Losanet AM. Consult your doctor before drinking alcohol. Alcohol may make your blood pressure fall too much and/or increase the possibility of dizziness or fainting.

Pregnancy and breast-feeding

Pregnancy

You must consult your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Losanet AM.

This medicine is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

Breast-feeding

Consult your doctor if you are breast-feeding or about to start breast-feeding. Amlodipine has been shown to pass into breast milk in small amounts. This medicine is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is a newborn or was born prematurely.

Use in children and adolescents

The use of Losanet AM in children and adolescents is not recommended (aged below 18 years old).

Driving and using machines

As with many other medicines used to treat high blood pressure, this medicine may make you feel dizzy. If you experience this symptom, do not drive or use tools or machines.

3. How to take Losanet AM

Always take this medicine exactly as your doctor has told you. You should consult your doctor if you are not sure.

The usual dose for adults of Losanet AM is one tablet per day.

- It is best to take the tablet at the same time each day.
- The tablets should be swallowed with a glass of water.
- Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Do not exceed the prescribed dose.
- You can take Losanet AM with or without food. Do not take Losanet AM with grapefruit or grapefruit juice.

Losanet AM and older people (age 65 years or over)

Your doctor should exercise caution when increasing your dose. If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

If you take more Losanet AM than you should

If you have taken too many tablets of Losanet AM, consult a doctor immediately. You may experience the following: fast heart beat (slow heart beat may also occur), low blood pressure.

If you forget to take Losanet AM

If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next tablet at the usual time. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Losanet AM

Stopping your treatment with Losanet AM may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to. Always take this medicine, even if you are feeling well.

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention.

If you experience the following, stop taking Losanet AM tablets and consult your doctor immediately or go to your nearest hospital:

- 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. You may need urgent medical attention or hospitalization.

Adverse drug reactions previously reported with one of the individual components (losartan potassium and amlodipine) may be potential undesirable effects with Losanet AM as well.

Losartan potassium

Common (may affect up to 1 in 10 people): dizziness, low blood pressure (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), dose-related orthostatic effects such as lowering of blood pressure appearing when rising from lying or sitting position, debility, fatigue, too little sugar in the blood (hypoglycemia), too much potassium in the blood (hyperkalemia), changes in kidney function including kidney failure, reduced number of red blood cells (anemia), increase in blood urea, serum creatinine and serum potassium in patients with heart failure.

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 (dyspnea), abdominal pain, obstipation, diarrhoea, nausea, vomiting, hives (urticaria), itching (pruritus), rash, localised swelling (oedema), cough.

Rare (may affect up to 1 in 1,000 people): hypersensitivity, angioedema, inflammation of blood vessels (vasculitis including Henoch-Schönlein 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 and joint pain, flu-like symptoms, back pain and urinary tract infection, increased sensitivity to the sun (photosensitivity), unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis), impotence, inflammation of the pancreas (pancreatitis), low levels of sodium in the blood (hyponatremia), depression, generally feeling unwell (malaise), ringing, buzzing, roaring, or clicking in the ears (tinnitus), disturbed taste (dysgeusia).

Amlodipine

Common (may affect 1 in 10 people): headache, dizziness, sleepiness (especially at the beginning of treatment), palpitations (awareness of your heart beat), flushing, abdominal pain, feeling sick (nausea), altered bowel habits, diarrhoea, constipation, indigestion; tiredness, weakness; visual disturbances, double vision; muscle cramp, ankle swelling.

Uncommon (may affect 1 in 100 people): mood changes, anxiety, depression, sleeplessness; trembling, taste abnormalities, fainting, numbness or tingling sensation in your limbs; loss of pain sensation; ringing in the ears; low blood pressure; sneezing/running nose caused by inflammation of the lining of the nose (rhinitis); cough, dry mouth, vomiting (being sick); hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration; 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 of men; pain, feeling unwell; joint or muscle pain, back pain; and weight increase or decrease.

Rare (may affect 1 in 1,000 people): confusion.

Very rare (may affect 1 in 10,000 people): 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 (hyperglycemia); a disorder of the nerves which can cause, muscular weakness, tingling or numbness; 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; and disorders combining rigidity, tremor, and/or movement disorders.

Not known (frequency cannot be estimated from the available data): trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Losanet AM

- Keep this medicine out of the sight and reach of children.
- Do not use Losanet AM after the expiry date which is stated on the outer box and blister. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Consult 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 Losanet AM contains

The active substances in Losanet AM are losartan potassium and amlodipine (as amlodipine besylate)

- Losanet AM 100 mg/5 mg tablets: Each tablet contains 100 mg losartan potassium and 5 mg amlodipine (as amlodipine besylate)

- Losanet AM 100 mg/10 mg tablets: Each tablet contains 100 mg losartan potassium and 10 mg amlodipine (as amlodipine besylate)

The other ingredients are: microcrystalline cellulose, magnesium stearate, maize starch, silica colloidal anhydrous, sodium starch glycolate and butylhydroxyanisol.

What Losanet AM looks like and contents of the pack

Losanet AM tablets are white oblong tablets.

Losanet AM 100 mg/5 mg is available in boxes containing 30 tablets.

Losanet AM 100 mg/10 mg is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

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This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

This leaflet was last revised in January 2022.

Council of Arab Health Ministers
Union of Arab Pharmacists