

Package leaflet: Information for the patient

Losanet AM Plus 100 mg/5 mg/12.5 mg Tablets

Losanet AM Plus 100 mg/10 mg/12.5 mg Tablets

Losartan potassium/amlodipine (as amlodipine besylate)/hydrochlorothiazide

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, talk your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Losanet AM Plus is and what it is used for
2. What you need to know before you take Losanet AM Plus
3. How to take Losanet AM Plus
4. Possible side effects
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1. What Losanet AM Plus is and what it is used for

Losanet AM Plus tablets contain three substances called losartan potassium, amlodipine and hydrochlorothiazide. All 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.
- Hydrochlorothiazide belongs to a group of substances called "thiazide diuretics". Hydrochlorothiazide increases urine output, which also lowers blood pressure.

As a result of all three mechanisms, the blood vessels relax and blood pressure is lowered.

Losanet AM Plus is used to treat high blood pressure in adult patients who are already taking losartan potassium, amlodipine and hydrochlorothiazide from separate tablets/capsules containing the same component doses and who may benefit from taking one tablet containing all three substances.

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

Do not take Losanet AM Plus:

- 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, hydrochlorothiazide, sulfonamide-derived medicines (medicines used to treat chest or urinary infections), or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, talk to your doctor.
- If you are, for more than 3 months pregnant, (It is also better to avoid Losanet AM Plus in early pregnancy - see Pregnancy section).
- If you have severe liver problems, such as liver disorders and jaundice (cholestasis).
- If you have severe kidney problems or if you are undergoing dialysis.
- If you are suffering from an inability to produce urine.
- If the level of potassium or sodium in your blood is too low despite treatment.
- If the level of calcium in your blood is too high despite treatment.
- If you have gout (uric acid crystals in the joints).
- If you suffer from severe hypotension or shock (including cardiogenic shock).
- If you suffer from obstruction of the outflow tract of the left ventricle (e.g. hypertrophic obstructive cardiomyopathy and high grade aortic stenosis).
- If you suffer from heart failure after a heart attack.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and precautions

Talk to your doctor before taking this medicine:

- If you have a low level of potassium or magnesium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm).
- If you have a low level of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- If you have a high level of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If you have kidney problems, have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- If you have liver problems.
- 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 you suffer from aldosteronism. This is a disease in which the adrenal glands make too much of the hormone aldosterone.
- If you suffer from a disease called systemic lupus erythematosus (also called "lupus" or "SLE").
- If you 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 you have diabetes (high level of sugar in your blood).
- If you experience skin reactions such as rash after sun exposure.
- If you had an allergic reaction to other high blood pressure medicines or diuretics (a type of medicine also known as "water tablets"), especially if you suffer from asthma and allergies.
- If you have been sick (vomiting or diarrhea).
- If you have experienced swelling, particularly of the face, lips, tongue and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking Losanet AM Plus and contact your doctor straight away. You should never take Losanet AM Plus.
- If you experience dizziness and/or fainting during treatment with Losanet AM Plus, tell your doctor as soon as possible.
- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (Choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Losanet AM Plus. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- 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.
- If you take diuretics (water pills).
- If you are on a salt-restricted diet.
- If you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function).
- If you have had gout.

- If you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets.
- If you have severe increase in blood pressure (hypertensive crisis).
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Losanet AM Plus.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

If any of these apply to you, talk to your doctor.

Children and adolescents under 18 years of age

Safety and effectiveness of Losanet Am Plus in pediatric patients has not been established.

Losanet AM Plus and older people (age 65 years and older)

Your doctor should exercise caution when increasing your dose. Elderly patients should have their blood pressure checked regularly.

Other medicines and Losanet AM Plus

Please tell 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 Plus 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 specially applies to the following medicines:

- Lithium (a medicine used to treat some types of depression).
- Medicines or substances that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- ACE inhibitors or aliskiren (see also information under the headings "Do not take Losanet AM Plus" and "Warnings and precautions").
- Alcohol, sleeping pills and anaesthetics (medicines allowing patients to undergo surgery and other procedures).
- Amantadine (anti-Parkinson therapy, also used to treat or prevent certain illnesses caused by viruses).
- Anticholinergic agents (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia).
- Anticonvulsant medicines and mood-stabilising medicines used to treat epilepsy and bipolar disorder (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone).
- Cholestyramine, colestipol or other resins (substances used mainly to treat high levels of lipids in the blood).
- Simvastatin (a medicine used to control high cholesterol levels).
- Ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g. rheumatoid arthritis or atopic dermatitis).
- Cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- Digoxin or other digitalis glycosides (medicines used to treat heart problems).
- Verapamil, diltiazem (used in the treatment of hypertension, angina pectoris and some types of arrhythmia).
- Iodine contrast media (agents used for imaging examinations).
- Medicines for the treatment of diabetes (oral agents such as metformin or insulins).
- Medicines for the treatment of gout, such as allopurinol.
- Medicines that may increase blood sugar levels (beta blockers, diazoxide).
- Medicines that may induce "torsades de pointes" (irregular heart beat), such as antiarrhythmics (medicines used to treat heart problems) and some antipsychotics.
- Medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- Medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, amphotericin or penicillin G.
- Medicines to increase blood pressure such as adrenaline or noradrenaline.
- Medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir).
- Medicines used to treat fungal infections (e.g. itraconazole, ketoconazole).
- Medicines used for oesophageal ulceration and inflammation (carbenoxolone).
- Medicines used to relieve pain or inflammation, especially Non-Steroidal Anti-Inflammatory Agents (NSAIDs), including selective Cyclooxygenase-2 inhibitors (Cox-2 inhibitors). Your doctor may also check your kidney function.
- Muscle relaxants (medicines to relax the muscles which are used during operations).
- Nitroglycerin and other nitrates, or other substances called "vasodilators".
- Other medicines to treat high blood pressure, including methyldopa.
- Medicines used to treat bacterial infections (such as rifampicin, erythromycin, clarithromycin, talithromycin)
- St. John's wort.
- Dantrolene (infusion for severe body temperature abnormalities).
- Vitamin D and calcium salts.
- Tacrolimus (medicine used to alter the way your immune system works).
- Opioid medicines such as morphine.

Losanet AM Plus with food, drink and alcohol

You can take Losanet AM Plus with or without food.

Grapefruit and grapefruit juice should not be consumed by people who are taking Losanet AM Plus. 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 Plus. Talk to 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 tell 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 Plus.

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

Tell your doctor if you are breast-feeding or about to start breast-feeding. 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.

Driving and using machines

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

3. How to take Losanet AM Plus

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

The usual dose of Losanet AM Plus 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.

If you take more Losanet AM Plus than you should

If you have accidentally taken too many Losanet AM Plus tablets, consult your 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 Plus

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 Plus

Stopping your treatment with Losanet AM Plus 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.

People who have high blood pressure often do not notice any signs of the problem. Many feel normal. It is very important that you take this medicine exactly as your doctor tells you to get the best results and reduce the risk of side effects. Keep your appointments with the doctor even if you are feeling well.

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

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 Plus 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).
- Heart attack, abnormal heart beat in case of high or low potassium level in the blood.
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

These are serious but rare side effects. You may need urgent medical attention or hospitalization.

Adverse drug reactions previously reported with one of the individual components (losartan potassium, amlodipine and hydrochlorothiazide) may be potential undesirable effects with Losanet AM Plus 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 a lying or sitting position, weakness, fatigue, too less 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, diarrhea, 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 (paresthesia), 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

Consult your doctor immediately if you experience any of the following very rare, severe side effects after taking this medicine:

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, diarrhea, constipation, indigestion, tiredness, weakness; visual disturbances, double vision; muscle cramps, 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.

Hydrochlorothiazide

Very common (may affect more than 1 in 10 people):

Low level of potassium in the blood, increase of lipids in the blood.

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

Low level of sodium in the blood; low level of magnesium in the blood; high level of uric acid in the blood; itchy rash and other types of rash; reduced appetite; mild nausea and vomiting; dizziness, fainting on standing up; inability to achieve or maintain erection.

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

Swelling and blistering of the skin (due to increased sensitivity to sun); high level of calcium in the blood; high level of sugar in the blood; sugar in the urine; worsening of diabetic metabolic state; constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes; irregular heart beat; headache; sleep disturbances; sad mood (depression); low level of blood platelets (sometimes with bleeding or bruising underneath the skin); dizziness; tingling or numbness; vision disorder.

Very rare (may affect up to 1 in 10,000 people):

Inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis); rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions); facial rash, joint pain, muscle disorder, fever (lupus erythematosus); severe upper stomach pain (pancreatitis); difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema); pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia); fever, sore throat or mouth ulcers due to infections (leukopenia); confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloremic alkalosis).

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

Weakness, bruising and frequent infections (aplastic anaemia); severely decreased urine output (possible signs of renal disorder or renal failure); rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme); muscle spasm; fever (pyrexia); weakness (asthenia); skin and lip cancer (non-melanoma skin cancer).

Reporting of 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 Plus

- Keep this medicine out of the sight and reach of children.
- Do not use Losanet AM Plus 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. 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 Losanet AM Plus contains

The active substances in Losanet AM Plus are losartan potassium, amlodipine (as amlodipine besylate) and hydrochlorothiazide.

- Losanet AM Plus 100 mg/5 mg/12.5 mg: Each tablet contains 100 mg losartan potassium, 5 mg amlodipine (as amlodipine besylate) and 12.5 mg hydrochlorothiazide.

- Losanet AM Plus 100 mg/10 mg/12.5 mg: Each tablet contains 100 mg losartan potassium, 10 mg amlodipine (as amlodipine besylate) and 12.5 mg hydrochlorothiazide.

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

What Losanet AM Plus looks like and contents of the pack

Losanet AM Plus tablets are white oblong plain tablets.

- Losanet AM Plus 100 mg/5 mg/12.5 mg: Box of 30 tablets.

- Losanet AM Plus 100 mg/10 mg/12.5 mg: Box of 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 buy or 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.

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Council of Arab Health Ministers
Union of Arab Pharmacists

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