

PATIENT COUNSELLING INFORMATION

^{Rx} Amlodipine and Lisinopril Tablets IP

Amlosafe- LS[®]

Read the entire leaflet carefully before you start taking this medicine:

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

1. What is Amlosafe- LS[®] and what is it used for?

Amlosafe-LS[®] is a combination of two medicines: Amlodipine, a calcium channel blocker (CCB) and Lisinopril, an angiotensin converting enzyme inhibitor (ACEi). Amlosafe- LS[®] is used to treat high blood pressure (hypertension) by relaxing blood vessels, so that blood flows through them more easily, thus reducing the effort needed to pump blood around the body.

2. What you need to know before you take Amlosafe- LS[®]?

Before you take Amlosafe- LS[®], tell your doctor:

- if you are allergic to Amlodipine, Lisinopril, any other calcium antagonists, any other angiotensin converting enzyme inhibitor (ACEi) e.g., captopril, enalapril, ramipril or any of the other ingredients of this medicine.
- if you have severe low blood pressure (hypotension).
- if the blood flow from the left side of your heart is obstructed (e.g., if you have narrowing of the aortic heart valve (aortic stenosis)).
- if you suffer from heart failure after a heart attack.
- if you suffer from cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you have ever had a severe allergic reaction to another ACE inhibitor. The allergic reaction may have caused skin rashes, itchy skin and swelling of the hands, ankles, face, lips, tongue or throat. It may have also made it difficult to swallow or breathe (angioedema).
- if a family member has ever had a severe allergic reaction (hereditary angioedema) or if you have previously had a severe allergic reaction of an unknown cause (idiopathic angioedema).

- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions

Tell your doctor about any prescription and non-prescription medicines you are taking, including natural or herbal remedies.

Tell your doctor before you take Amlosafe- LS[®] if you have, or have had, any of the following conditions:

- Severe increase in blood pressure (Hypertensive crisis).
- Liver disease.
- Dehydration due to treatment with diuretic medicine, dialysis, dietary restriction of salt, vomiting or diarrhoea. You may be more likely to suffer from a very large drop in blood pressure when you start taking the tablets and may feel faint or light headed.
- Abnormal functioning of the heart, heart failure or heart valve disease, narrowing (stenosis) or hardening of the arteries of your heart or an enlarged heart (known as hypertrophic cardiomyopathy).
- Stroke or mini-stroke [also known as transient ischaemic attack (TIA)].
- Kidney disease, improper functioning of the kidneys or narrowing (stenosis) of the blood vessels to the kidney then your dosage may need to be adjusted.
- Kidney dialysis treatment or kidney transplant.
- Blood separation treatment (apheresis) e.g., for high cholesterol levels or desensitisation treatment e.g., following a wasp or bee sting; your doctor may wish to interrupt your Amlosafe- LS[®] treatment to prevent a possible allergic reaction.
- Collagen vascular disease e.g., scleroderma, SLE or lupus (an allergic condition causing joint pain, skin rashes and fever). Your doctor may perform frequent blood tests to check for any infections that may develop during treatment.
- Diabetes.
- High levels of potassium in your blood (hyperkalaemia).
- If you are taking any of the following medicines used to treat high blood pressure:

- an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
- aliskiren.

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

During treatment, talk to your doctor if you develop a dry cough which is persistent for a long time after starting treatment with Amlosafe-LS[®].

Children and adolescents: Amlodipine (2.5 to 5 mg daily) is effective in lowering blood pressure in patients 6 to 17 years. Effect of Amlodipine on blood pressure in patients less than 6 years of age is not known. Antihypertensive effects and safety of Lisinopril have been established in pediatric patients aged 6 to 16 years. No relevant differences between the adverse reaction profile for pediatric patients and adult patients were identified. Safety and effectiveness of Amlodipine and Lisinopril have not been established in pediatric patients under the age of 6 years or in pediatric patients with glomerular filtration rate < 30 mL/min/1.73 m².

For more information, talk to your doctor.

Other medicines and Amlosafe- LS[®]

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

Tell your doctor about all your other medicines, especially:

- nitroglycerin;
- simvastatin or any other heart or blood pressure medications.
- medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
- diuretics ('water tablets') e.g., amiloride, triamterene, spironolactone.
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and cotrimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- insulin or other medicines for diabetes taken by mouth e.g., gliclazide, metformin; your blood glucose should be monitored closely in the first month of starting Lisinopril.
- angiotensin II receptor blocker (ARB) or aliskiren.

- Lithium
- medicines containing gold e.g., sodium aurothiomalate, which may be given to you by injection for conditions such as arthritis.
- NSAIDs – aspirin, ibuprofen, naproxen, celecoxib, diclofenac, indomethacin, meloxicam and others.

This list is not complete. Other drugs may affect Amlodipine, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Driving and using machines

Caution is recommended, especially at the start of treatment with Amlosafe- LS[®].

Pregnancy and breast-feeding: If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

3. How to take Amlosafe- LS[®]?

Take Amlosafe- LS[®] once a day, with or without food.

It may be easier to take your dose if you do it at the same time every day, such as with breakfast or dinner, or at bedtime. Do not take more than one dose of Amlosafe- LS[®] at a time.

If you take more Amlosafe- LS[®] than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak or have a rapid heartbeat. If blood pressure drop is severe enough, shock can occur. Your skin could feel cool and clammy and you could lose consciousness, kidney failure, changes in blood salts which may be seen in blood tests, difficulty breathing increased or decreased heartbeat, dizziness, anxiety and cough. Seek immediate medical attention if you take too many Amlodipine tablets.

If you forget to take Amlosafe- LS[®]?

If you forget to have a dose, have it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. This may increase the chance of you getting an unwanted side effect.

If you stop taking **Amlosafe- LS[®]**

Do not suddenly stop taking your medicine. 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 the use of this medicine, ask your doctor.

4. What are the possible side effects of Amlosafe- LS[®]?

Amlosafe- LS[®] may cause the following side effects. Most side effects are mild or moderate:

- swelling of your legs or ankles
- tiredness, extreme sleepiness
- stomach pain, nausea
- dizziness
- flushing (hot or warm feeling in your face)
- arrhythmia (irregular heartbeat)
- heart palpitations (very fast heartbeat)
- muscle rigidity, tremor and/or abnormal muscle movement
- lightheadedness,
- fever,
- sore throat,
- weakness,
- tingly feeling,
- chest pain,
- little or no urination,
- short of breath,
- upper stomach pain,
- itching,
- loss of appetite,
- dark urine,
- clay-colored stools, and
- yellowing of the skin or eyes (jaundice)
- headache,
- cough

This is not a complete list of side effects and others may occur. If you notice any side-effects mentioned above, please tell your doctor.

If any of the side-effects become severe, or if you notice any side-effects not listed in the leaflet, please tell your doctor immediately.

5. How to store Amlosafe- LS[®]?

Store protected from moisture.

Keep out of reach of children.

Do not use this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.

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