

CAMLO-L

(Amlodipine 5 mg + Losartan Potassium 50 mg Tablets)

PATIENT INFORMATION LEAFLET (PIL)

Read this leaflet carefully before taking this medicine.

1. What is Camlo-L and what is it used for?

Camlo-L contains two active substances: Amlodipine (a calcium channel blocker) and Losartan Potassium (an angiotensin II receptor blocker – ARB). It is used to treat high blood pressure (hypertension) and helps prevent strokes, heart attacks, and kidney problems.

2. Who should NOT take Camlo-L?

Do NOT take Camlo-L if you:

- Are allergic to amlodipine, losartan, or any of the other ingredients.
- Have severely low blood pressure (hypotension).
- Have narrowing of the aortic heart valve (aortic stenosis).
- Are pregnant or planning to become pregnant.
- Have severe liver or kidney problems.

3. How should I take Camlo-L?

Take one tablet once daily. Swallow the tablet with water at the same time each day. You can take it with or without food.

Missed a dose? Take it as soon as you remember. If it is near your next dose, skip the missed one. Do NOT double dose.

4. What are the possible side effects?

Common:

- Dizziness, tiredness
- Swelling in ankles or feet
- Headache
- Muscle cramps

Serious (Seek medical help):

- Chest pain or irregular heartbeat
- Severe allergic reactions
- Yellowing of the skin/eyes (jaundice)

5. What should I do if I feel dizzy or faint?

Sit or lie down immediately. Rise slowly from sitting or lying positions. Drink plenty of fluids unless advised otherwise.

6. Can I take Camlo-L with other medicines?

Tell your doctor if you are taking:

- Other blood pressure medicines
- Potassium supplements or salt substitutes
- Lithium
- NSAIDs (e.g. Ibuprofen)
- Diuretics
- Antibiotics like Rifampicin

7. What precautions should I take?

Avoid alcohol—it may lower blood pressure further.

Inform your doctor if you have heart, kidney, or liver disease.

If pregnant or breastfeeding, this medicine should NOT be used.

8. How should I store Camlo-L?

Store below 30°C in a dry place. Keep out of reach of children. Do not use after the expiry date.

CAMLO-L

(Amlodipine 5 mg + Losartan Potassium 50 mg Tablets)

FOR HEALTHCARE PROFESSIONALS

COMPOSITION

Camlo-L: Each film-coated tablet contains: Amlodipine Besylate equivalent to Amlodipine 5 mg and Losartan Potassium IP 50 mg

DESCRIPTION

Camlo-L combines two antihypertensives with complementary mechanisms:

- Amlodipine: a calcium-channel blocker reducing vascular resistance.
- Losartan: an angiotensin II receptor blocker reducing vasoconstriction and aldosterone effects.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties:

Camlo-L is the combination of two drugs: Amlodipine [Calcium Channel Blocker (CCB)] and Losartan [Angiotensin Receptor Blocker (ARB)].

Amlodipine is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.

Losartan is a synthetic oral angiotensin-II receptor (type AT1) antagonist. Angiotensin II, a potent vasoconstrictor, is the primary active hormone of the renin/angiotensin system and an important determinant of the pathophysiology of hypertension. Angiotensin II binds to the AT1 receptor found in many tissues (e.g. vascular smooth muscle, adrenal gland, kidneys and the heart) and elicits several important biological actions, including vasoconstriction and the release of aldosterone. Angiotensin II also stimulates smooth muscle cell proliferation.

Pharmacokinetic properties:

Amlodipine

Absorption: Absorption produces peak plasma concentrations between 6 to 12 hours after oral administration of therapeutic doses of Amlodipine alone, post dose. Absolute bioavailability has been estimated to be between 64 and 80 %. The bioavailability of Amlodipine is not altered by the presence of food.

Distribution: In vitro studies with Amlodipine have shown that approximately 97.5% of the circulating drug is bound to plasma proteins in hypertensive patients.

Metabolism: Amlodipine is extensively (about 90%) converted to inactive metabolites via hepatic metabolism.

Elimination: Elimination of Amlodipine from the plasma is biphasic with a terminal elimination half-life of about 30-50 hours. Steady state plasma levels are reached after 7 to 8 days of consecutive dosing. 10% of the parent Amlodipine compound and 60% of the metabolites of Amlodipine are excreted in the urine.

Losartan

Absorption

Following oral administration, losartan is well absorbed and undergoes first pass metabolism, forming an active carboxylic acid metabolite and other inactive metabolites. The systemic

bioavailability of losartan tablets is approximately 33%. Mean peak concentrations of losartan and its active metabolite are reached in 1 hour and in 3-4 hours, respectively.

Distribution

Both losartan and its active metabolite are $\geq 99\%$ bound to plasma proteins, primarily albumin. The volume of distribution of losartan is 34 litres.

Biotransformation

About 14% of an intravenously or orally administered dose of losartan is converted to its active metabolite. Following oral and intravenous administration of ^{14}C labelled losartan potassium, circulating plasma radioactivity primarily is attributed to losartan and its active metabolite. Minimal conversion of losartan to its active metabolite was seen in about 1% of individuals studied.

In addition to the active metabolite, inactive metabolites are formed.

Elimination

Plasma clearance of losartan and its active metabolite is about 600 ml/min and 50 ml/min, respectively. Renal clearance of losartan and its active metabolite is about 74 ml/min and 26 ml/min, respectively.

When losartan is administered orally, about 4% of the dose is excreted unchanged in the urine, and about 6% of the dose is excreted in the urine as active metabolite. The pharmacokinetics of losartan and its active metabolite are linear with oral losartan potassium doses up to 200 mg.

Following oral administration, plasma concentrations of losartan and its active metabolite decline polyexponentially, with a terminal half life of about 2 hours and 6-9 hours, respectively. During once daily dosing with 100 mg, neither losartan nor its active metabolite accumulates significantly in plasma.

Both biliary and urinary excretions contribute to the elimination of losartan and its metabolites. Following an oral dose/intravenous administration of ^{14}C labelled losartan in man, about 35% / 43% of radioactivity is recovered in the urine and 58% / 50% in the faeces.

- Amlodipine: Peak plasma 6–12 hrs, Half-life ~30–50 hrs, hepatic metabolism.
- Losartan: Peak plasma 1 hr (active metabolite 3–4 hrs), Half-life ~2–9 hrs, excreted in urine and bile.

THERAPEUTIC INDICATIONS

Treatment of essential hypertension in patients requiring dual therapy.

POSODOLOGY & ADMINISTRATION

One tablet once daily, with or without food. Adjust dose in hepatic impairment.

CONTRAINDICATIONS

Amlodipine is contraindicated in patients with:

- hypersensitivity to dihydropyridine derivatives, amlodipine or to any of the excipients
- severe hypotension
- shock (including cardiogenic shock)
- obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis)
- haemodynamically unstable heart failure after acute myocardial infarction

Losartan

- Hypersensitivity to the active substance or to any of the excipients
- 2nd and 3rd trimester of pregnancy
- Severe hepatic impairment.
- The concomitant use of Losartan potassium with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²)

SPECIAL POPULATION

Losartan

Renal impairment

As a consequence of inhibiting the renin-angiotensin system, changes in renal function including renal failure have been reported (in particular, in patients whose renal function is dependent on the renin-angiotensin-aldosterone system such as those with severe cardiac insufficiency or pre-existing renal dysfunction). As with other medicinal products that affect the renin-angiotensin-aldosterone system, increases in blood urea and serum creatinine have also been reported in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney; these changes in renal function may be reversible upon discontinuation of therapy. Losartan should be used with caution in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney.

Hepatic impairment

Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose should be considered for patients with a history of hepatic impairment. There is no therapeutic experience with losartan in patients with severe hepatic impairment. Therefore losartan must not be administered in patients with severe hepatic impairment.

Losartan is not recommended in children with hepatic impairment.

Pregnancy

Losartan should not be initiated during pregnancy. Unless continued losartan therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with losartan should be stopped immediately, and, if appropriate, alternative therapy should be started

Coronary heart disease and cerebrovascular disease

As with any antihypertensive agents, excessive blood pressure decrease in patients with ischaemic cardiovascular and cerebrovascular disease could result in a myocardial infarction or stroke.

Heart failure

In patients with heart failure, with or without renal impairment, there is as with other medicinal products acting on the renin angiotensin system a risk of severe arterial hypotension, and (often acute) renal impairment.

There is no sufficient therapeutic experience with losartan in patients with heart failure and concomitant severe renal impairment, in patients with severe heart failure (NYHA class IV) as well as in patients with heart failure and symptomatic life threatening cardiac arrhythmias. Therefore, losartan should be used with caution in these patient groups. The combination of losartan with a beta-blocker should be used with caution.

Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy

As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.

Amlodipine

The safety and efficacy of amlodipine in hypertensive crisis has not been established.

Cardiac failure:

Patients with heart failure should be treated with caution. In a long-term, placebo controlled study in patients with severe heart failure (NYHA class III and IV) the reported incidence of pulmonary oedema was higher in the amlodipine treated group than in the placebo group. Calcium channel blockers, including amlodipine, should be used with caution in patients with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality.

Hepatic impairment:

The half-life of amlodipine is prolonged and AUC values are higher in patients with impaired liver function; dosage recommendations have not been established. Amlodipine should therefore be initiated at the lower end of the dosing range and caution should be used, both on initial treatment and when increasing the dose. Slow dose titration and careful monitoring may be required in patients with severe hepatic impairment.

Elderly

In the elderly increase of the dosage should take place with care.

Renal impairment:

Amlodipine may be used in such patients at normal doses. Changes in amlodipine plasma concentrations are not correlated with degree of renal impairment. Amlodipine is not dialyzable.

WARNINGS & PRECAUTIONS

- Monitor renal function
- Watch for angioedema
- Monitor potassium levels

INTERACTIONS

- Avoid potassium supplements
- NSAIDs may reduce effect
- CYP3A4 inhibitors affect amlodipine

PREGNANCY & LACTATION

- Contraindicated in pregnancy.
- Not recommended during breastfeeding.

SIDE EFFECTS

- Common: Edema, dizziness, fatigue
- Serious: Hypotension, renal impairment, liver enzyme increase

STORAGE

Store below 30°C in a dry place. Keep out of reach of children.

This content was last revised in August 2025.

***National
Healthcare***