For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Amlodipine and Losartan Potassium Tablets IP
(Brand Name: ANGICAM®-LT Tablets)

2. Qualitative and Quantitative Composition

Each film coated tablet contains:
Amlodipine Besylate IP equivalent to Amlodipine …… 5 mg.
Losartan Potassium IP ……..… 50 mg.
Excipients …… q.s.
Colours: Quinoline Yellow and Titanium Dioxide IP.

3. Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Amlodipine 5 mg and losartan potassium 50 mg per tablet.

4. Clinical Particulars

4.1 Therapeutic Indication

ANGICAM-LT Tablets are indicated for the treatment of essential hypertension, particularly when blood pressure is not adequately controlled by monotherapy of either drug.

4.2Posology and Method of Administration

For oral administration.
Adults: The usual initial dosage is 1 tablet once daily. If blood pressure goal is not achieved within 4 weeks, the dose may be increased to 2 tablets once daily. The dosage, however, should be individualized.
Amlodipine is effective in doses between 2.5 mg to maximum 10 mg once daily.
Losartan is effective in doses between 25 mg to maximum 100 mg once daily.
ANGICAM-LT Tablets can be administered with or without food.
Or, as prescribed by the physician.

4.3Contraindications

ANGICAM-LT Tablets are contraindicated in patients who are hypersensitive to amlodipine or to losartan potassium or to any component of this formulation.

4.4Special Warnings and Precautions for Use

Hypotension: In patients with intravascular volume- or salt-depletion (e.g., those treated with high-dose diuretics) or with severe aortic stenosis, symptomatic hypotension may occur. Intravascular volume depletion should be corrected prior to administration of ANGICAM-LT Tablets, or a lower starting dose should be used. Because of the gradual onset of action of amlodipine, acute hypotension is unlikely.

Liver Function Impairment: Based on pharmacokinetic data which demonstrate significantly increased plasma concentrations of losartan in cirrhotic patients, a lower dose of losartan should be considered for patients with a history of hepatic impairment.

Because amlodipine is extensively metabolized by the liver and the plasma elimination half-life (t1/2) is 56 hours in patients with impaired hepatic function, titrate slowly when administering amlodipine to patients with severe hepatic impairment.

Additional Warnings and Precautions for Individual Components

Amlodipine

Increased Angina or Myocardial Infarction: Worsening of angina and acute myocardial infarction can develop after starting or increasing the dose of amlodipine, particularly in patients with severe obstructive coronary artery disease.

Congestive Heart Failure: In general, calcium channel blockers should be used with caution in patients with heart failure.

Losartan

Renal Function Deterioration: This combination therapy should be used with caution in patients with severe renal disease. As a consequence of inhibiting the RAAS, changes in renal function have been reported in susceptible individuals treated with losartan; in some patients, these changes in renal function were reversible upon discontinuation of therapy.

In patients whose renal function may depend on the activity of the RAAS (e.g., patients with severe congestive heart failure), losartan treatment has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure and/or death. Also, losartan treatment in patients with unilateral or bilateral renal artery stenosis was associated with increases in serum creatinine or blood urea nitrogen (BUN). In some patients, these effects were reversible upon discontinuation of therapy.

Electrolyte Imbalance/Hyperkalemia: Electrolyte imbalances are common in patients with renal impairment, with or without diabetes, and should be addressed. In a clinical study conducted in type 2 diabetic patients with proteinuria, the incidence of hyperkalemia was higher in the group treated with losartan as compared to the placebo group; however, only a few patients discontinued therapy due to hyperkalemia. Serum potassium should be monitored periodically and treated appropriately. Dosage reduction or discontinuation of losartan may be required.

4.5Drug Interactions

Amlodipine

1. Impact of Other Drugs on Amlodipine

Sildenafil: Hypotensive effect is enhanced when amlodipine is given with sildenafil. Monitor for hypotension when these drugs are given together.

CYP3A Inhibitors (e.g., Ketoconazole, Itraconazole, Diltiazem, Erythromycin, Fluconazole, etc.): Co-administration with CYP3A inhibitors results in increased systemic exposure to amlodipine and may require dose reduction. Monitor for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A inhibitors to determine the need for dose adjustment.

CYP3A Inducers (e.g., Carbamazepine, Phenytoin, Rifampin, etc.): No information is available on the quantitative effects of CYP3A inducers on amlodipine. Blood pressure and edema should be closely monitored when amlodipine is co-administered with CYP3A inducers.

2. Impact of Amlodipine on Other Drugs

Simvastatin: Co-administration of simvastatin with amlodipine increases the systemic exposure of simvastatin. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

Immunosuppressants: Amlodipine may increase the systemic exposure of cyclosporine or tacrolimus when co-administered. Frequent monitoring of blood levels of cyclosporine and tacrolimus and dosage adjustment (whenever appropriate) is recommended.

Losartan

Agents Increasing Serum Potassium: Co-administration of losartan with other drugs that raise serum potassium levels may result in hyperkalemia. Monitor serum potassium in such patients.

Lithium: Increase in serum lithium concentration and lithium toxicity has been reported during concomitant administration of lithium with angiotensin II receptor antagonists (e.g., losartan). Monitor serum lithium levels during concomitant use.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Including Selective Cyclooxygenase-2 Inhibitors (COX-2 Inhibitors): In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with angiotensin II receptor antagonists (including losartan) may result in deterioration of renal function, including possible acute renal failure. These effects are usually reversible. Monitor renal function periodically in patients receiving losartan and NSAID therapy. The antihypertensive effect of angiotensin II receptor antagonists, including losartan, may be attenuated by NSAIDs, including selective COX-2 inhibitors.

Dual Blockade of the Renin-Angiotensin Aldosterone System (RAAS): Dual blockade of the RAAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy.

In most patients no benefit has been associated with using two RAAS inhibitors concomitantly. In general, avoid combined use of RAAS inhibitors. Closely monitor blood pressure, renal function, and electrolytes in patients on losartan and other agents that affect the RAAS.
Aliskiren: Do not co-administer aliskiren with losartan in patients with diabetes. Avoid use of aliskiren with losartan in patients with renal impairment (GFR <60 ml/min).

4.6Use in Special Populations

Pregnant Women

Amlodipine: Pregnancy Category C; Losartan: Pregnancy Category D. The safety of amlodipine in human pregnancy has not been established. In animal studies, reproductive toxicity was observed at high doses. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin aldosterone system - RAAS (e.g., losartan) can cause injury and even death in the developing fetus. Thus, when pregnancy is detected or planned, ANGICAM-LT Tablets should be discontinued as soon as possible.

Lactating Women

Limited available data from a published clinical study reports that amlodipine is present in human milk. It is not known whether losartan is excreted in human milk. Because many drugs are excreted in human milk and have potential for causing adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Paediatric Patients

Safety and efficacy of this formulation has not been established in paediatric patients. Thus, ANGICAM-LT Tablets are not recommended for use in children.

Geriatric Patients

Elderly patients have decreased clearance of amlodipine with a resulting increase in area under the plasma drug concentration-time curve (AUC) to approximately 40 to 60%. With losartan, no overall differences in effectiveness or safety were observed between elderly patients and younger patients. In general, dose selection for an elderly patient should be cautious and usually a lower initial dose may be required, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant diseases and/or other drug therapy.

Renal Impairment Patients

The pharmacokinetics of amlodipine is not significantly influenced by renal impairment. Patients with renal failure, therefore, may receive the usual initial dose.
Plasma concentrations and AUCs of losartan and its active metabolite are increased by 50 to 90% in patients with mild or moderate renal insufficiency. However, no dosage adjustment of losartan is necessary in these patients unless they are volume-depleted.

Thus, ANGICAM-LT Tablets can be administered in a patient with mild to moderate renal impairment. Due to lack of safety data, ANGICAM-LT Tablets are not recommended in patients with severe renal impairment or patients on dialysis.

Hepatic Impairment Patients

Patients with hepatic insufficiency have decreased clearance of amlodipine with a resulting increase in AUC of approximately 40 to 60%. A similar increase in AUC has been observed in patients with moderate to severe heart failure. Thus, a lower initial dose (2.5 mg) amlodipine is preferable in this condition.

In patients with mild-to-moderate hepatic impairment, plasma concentrations of losartan and its active metabolite increased by 5 times and 1.7 times, respectively. Plasma clearance of losartan in patients with hepatic insufficiency was about 50% lower and the oral bioavailability was about 2 times higher. Thus, a lower starting dose (25 mg) of losartan is recommended in patients with mild-to-moderate hepatic impairment.

Safety of this formulation has not been studied in patients with severe hepatic impairment and thus, ANGICAM-LT Tablets are not recommended in this condition.

Use in Patients with Intravascular Volume Depletion

Use of ANGICAM-LT Tablets is not recommended for patients with intravascular volume-depletion (e.g., those treated with high-dose diuretics).

4.7Effect on Ability to Drive and Use Machines

With losartan no studies on the effects on the ability to drive and use machines have been performed. Amlodipine can have minor or moderate influence on the ability to drive and use machines. Dizziness or drowsiness may occasionally occur when taking this medicine. Thus, caution is recommended in particular during initiation of treatment or when the dose is increased.

4.8Undesirable Effects

Amlodipine

Most common adverse reactions reported with amlodipine are headache and pedal edema. Adverse effects with an incidence >1% in clinical studies included abdominal pain, nausea, dizziness, somnolence, flushing, palpitations, and fatigue.

Rare adverse events observed in controlled clinical trials or open trials or post-marketing surveillance studies (causal relationship is uncertain) included:

Cardiovascular: Arrthythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, postural hypotension, vasculitis, cardiac failure, pulse irregularity, extrasystoles.

Central and Peripheral Nervous System: Hypoesthesia, peripheral neuropathy, paresthesia, tremor, vertigo, ataxia, hypertonia, migraine, apathy, agitation, amnesia.

Gastrointestinal: Anorexia, constipation, dysphagia, diarrhea, flatulence, gastritis, increased appetite, loose stools, pancreatitis, vomiting, gingival hyperplasia/hypertrophy.
Musculoskeletal System: Arthralgia, arthrosis, muscle cramps, myalgia, muscle weakness, twitching.
Psychiatric: Sexual dysfunction, insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization.
Respiratory System: Dyspnea, epistaxis, cough, rhinitis.
Skin and Appendages: Rash, pruritus, urticaria, angioedema, skin dryness, alopecia, skin discoloration.
Special Senses: Abnormal vision, conjunctivitis, diplopia, eye pain, abnormal visual accommodation, xerophthalmia, tinnitus, parosmia, taste perversion.
Urinary System: Increased micturition frequency, nocturia, dysuria, polyuria.
Autonomic Nervous System: Dry mouth, increased sweating, cold and clammy skin.
Metabolic and Nutritional: Hyperglycemia, thirst.
Hemopoietic: Leukopenia, purpura, thrombocytopenia.
General: Allergic reaction, back pain, hot flushes, malaise, pain, rigors, weight gain, weight loss.

Losartan

Clinical Trials Experience

The adverse events that occurred in ≥2% of patients treated with losartan and more commonly than placebo were dizziness, upper respiratory infection, nasal congestion, and back pain.
The following adverse reactions have been reported less frequently:
Blood and Lymphatic System: Anemia.
Psychiatric: Depression.
Nervous System: Somnolence, headache, sleep disorders, paresthesia, migraine.
Ear and Labyrinth: Vertigo, tinnitus.
Cardiac: Palpitations, syncope, atrial fibrillation, cerebrovascular accidents.
Respiratory, Thoracic and Mediastinal: Dyspnea.
Gastrointestinal: Abdominal pain, constipation, nausea, vomiting.
Skin and Subcutaneous Tissue: Urticaria, pruritus, rash, photosensitivity.
Musculoskeletal and Connective Tissue: Myalgia, arthralgia.
Reproductive System: Impotence.
General Disorders and Administration Site Conditions: Edema.

Post-Marketing Experience

Digestive: Hepatitis.
General Disorders and Administration Site Conditions: Malaise.
Hematologic: Thrombocytopenia.

Hypersensitivity: Angioedema, including swelling of the larynx and glottis, causing airway obstruction and/or swelling of the face, lips, pharynx, and/or tongue has been reported rarely in patients treated with losartan.
Metabolic and Nutrition: Hyponatremia.
Musculoskeletal: Rhabdomyolysis, muscle spasm.
Nervous System: Dysgeusia.
Skin: Erythroderma.

4.9Overdose

Amlodipine

Overdose might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdose of amlodipine is limited.

If massive overdose should occur, initiate active cardiac and respiratory monitoring. Frequent blood pressure measurements are essential. Should hypotension occur, provide cardiovascular support including elevation of the extremities and the judicious administration of fluids. If hypotension remains unresponsive to these conservative measures, consider administration of vasopressors (such as phenylephrine) with attention to circulating volume and urine output. As amlodipine is highly protein bound, hemodialysis is not likely to be of benefit.

Losartan

Limited data is available with regard to overdose in humans. The most likely manifestation of overdose would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. Neither losartan nor its active metabolite can be removed by hemodialysis.

5. Pharmacological Properties

5.1 Mechanism of Action

Amlodipine

Amlodipine is a dihydropyridine class of long-acting calcium channel blocker – CCB (calcium antagonist). Amlodipine inhibits the transmembrane influx of calcium ions (Ca^{++}) into vascular smooth muscle and cardiac muscle.

Experimental data suggest that amlodipine binds to both dihydropyridine and nondihydropyridine binding sites. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Serum calcium concentration is not affected by amlodipine.

Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Losartan

Angiotensin II [formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II)] is a potent vasoconstrictor, the primary vasoactive hormone of the renin-angiotensin aldosterone system, and an important component in the pathophysiology of hypertension. It also stimulates aldosterone secretion by the adrenal cortex. Losartan and its principal active metabolite block the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor found in many tissues, (e.g., vascular smooth muscle, adrenal gland).

Both, losartan and its active metabolite, have much greater affinity (about 1000-fold) for the AT1 receptor than for the AT2 receptor. *In vitro* binding studies indicate that losartan is a reversible, competitive inhibitor of the AT1 receptor. The active metabolite is 10 to 40 times more potent than losartan and appears to be a reversible, non-competitive inhibitor of the AT1 receptor.

5.2Pharmacodynamic Properties

Amlodipine

Following administration of therapeutic doses to patients with hypertension, amlodipine produces vasodilation resulting in a reduction of supine and standing blood pressures. With chronic once daily oral administration, antihypertensive effectiveness is maintained for at least 24 hours. These decreases in blood pressure are not accompanied by a significant change in heart rate or plasma catecholamine levels with chronic dosing.

Losartan

Losartan inhibits the pressor effect of angiotensin II (as well as angiotensin I) infusions. A dose of 100 mg inhibits the pressor effect by about 85% at peak with 25-40% inhibition persisting for 24 hours. Removal of the negative feedback of angiotensin II causes a doubling to tripling in plasma renin activity and consequent rise in angiotensin II plasma concentration in hypertensive patients. Aldosterone plasma concentrations fall following losartan administration. In spite of the effect of losartan on aldosterone secretion, very little effect on serum potassium was observed.

The effect of losartan is substantially present within one week but in some studies the maximal effect occurred in 3 to 6 weeks. In long-term follow-up studies (without placebo control) the effect of losartan appeared to be maintained for up to a year. There is no apparent rebound effect after abrupt withdrawal of losartan. There was essentially no change in average heart rate in losartan-treated patients in controlled trials.

5.3Pharmacokinetic Properties

Amlodipine

Absorption: After oral administration of therapeutic doses, amlodipine produces peak plasma concentrations between 6 to 12 hours. Absolute bioavailability has been estimated to be between 64 to 90%. The bioavailability is not altered by the presence of food.

Distribution: The volume of distribution is approximately 21 l/kg. *Ex vivo* studies have shown that approximately 93% 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 with 10% of the parent compound and 60% of the metabolites excreted in the urine.
Excretion: Excretion from the plasma is biphasic with a terminal elimination half-life of about 30 to 50 hours. Steady-state plasma levels of amlodipine are reached after 7 to 8 days of consecutive daily dosing.

Losartan
Absorption: Following oral administration, losartan is well absorbed and undergoes substantial first-pass metabolism. The systemic bioavailability of losartan is approximately 33%. Mean peak concentrations of losartan and its active metabolite are reached in 1 hour and in 3 to 4 hours, respectively. While maximum plasma concentrations of losartan and its active metabolite are approximately equal, the AUC (area under the curve) of the metabolite is about 4 times as great as that of losartan. A meal slows absorption of losartan and decreases its C_{max}, but has only minor effects on losartan AUC or on the AUC of the metabolite (~10% decrease). The pharmacokinetics of losartan and its active metabolite are linear with oral losartan doses up to 200 mg and do not change over time.
Distribution: The volume of distribution of losartan and the active metabolite is about 34 liters and 12 liters, respectively. Both losartan and its active metabolite are highly bound to plasma proteins, primarily albumin, with plasma-free fractions of 1.3% and 0.2%, respectively. Plasma protein binding is constant over the concentration range achieved with recommended doses.
Metabolism: Losartan that undergoes substantial first-pass metabolism by cytochrome P450 enzymes. It is converted, in part, to an active carboxylic acid metabolite that is responsible for most of the angiotensin II receptor antagonism that follows losartan treatment. About 14% of an orally-administered dose of losartan is converted to the active metabolite. In addition to the active carboxylic acid metabolite, several inactive metabolites are formed. *In vitro* studies indicate that cytochrome P450 2C9 and 3A4 are involved in the biotransformation of losartan to its metabolites.
Excretion: Total plasma clearance of losartan and the active metabolite is about 600 ml/min and 50 ml/min respectively, with renal clearance of about 75 ml/min and 25 ml/min respectively. The terminal half-life of losartan is about 2 hours and that of the metabolite is about 6 to 9 hours. After single doses of losartan administered orally, about 4% of the dose is excreted unchanged in the urine and about 6% is excreted in urine as active metabolite. Biliary excretion contributes to the elimination of losartan and its metabolites. Following oral 14C-labeled losartan, about 35% of the radioactivity is recovered in the urine and about 60% in the feces. Neither losartan nor its metabolite accumulates in plasma upon repeated once-daily dosing.

6. Nonclinical Properties
6.1 Animal Toxicology

Amlodipine

Carcinogenesis: Rats and mice treated with amlodipine in the diet for up to two years, at concentrations calculated to provide daily dosage levels of 0.5, 1.25, and 2.5 amlodipine mg/kg/day, showed no evidence of a carcinogenic effect of the drug.

Mutagenesis: Mutagenicity studies conducted with amlodipine revealed no drug related effects at either the gene or chromosome level.

Impairment of Fertility: There was no effect on the fertility of rats treated orally with amlodipine (males for 64 days and females for 14 days prior to mating) at doses up to 10 mg amlodipine/kg/day (8 times [based on body weight of 50 kg] the maximum recommended human dose of 10 mg/day on a mg/m^2 basis).

Teratogenicity: No evidence of teratogenicity or other embryo/fetal toxicity was found when pregnant rats and rabbits were treated orally with amlodipine at doses up to 10 mg amlodipine/kg/day (approximately 10 and 20 times the maximum recommended human dose based on body surface area, respectively) during their respective periods of major organogenesis. However for rats, litter size was significantly decreased (by about 50%) and the number of intrauterine deaths was significantly increased (about 5-fold) in rats receiving amlodipine at a dose equivalent to 10 mg amlodipine/kg/day for 14 days before mating and throughout mating and gestation. Amlodipine has been shown to prolong both the gestation period and the duration of labor in rats at this dose.

Losartan

Carcinogenesis: Losartan potassium was not carcinogenic when administered at maximally tolerated dosages to rats and mice for 105 and 92 weeks, respectively. Female rats given the highest dose (270 mg/kg/day) had a slightly higher incidence of pancreatic acinar adenoma. The maximally tolerated dosages (270 mg/kg/day in rats, 200 mg/kg/day in mice) provided systemic exposures for losartan and its pharmacologically active metabolite that were approximately 160 and 90 times (rats) and 30 and 15 times (mice) the exposure of a 50 kg human given 100 mg per day.

Mutagenesis: Losartan potassium was negative in the microbial mutagenesis and V-79 mammalian cell mutagenesis assays and in the *in vitro* alkaline elution and *in vitro* and *in vivo* chromosomal aberration assays. In addition, the active metabolite showed no evidence of genotoxicity in the microbial mutagenesis, *in vitro* alkaline elution, and *in vitro* chromosomal aberration assays.

Impairment of Fertility: Fertility and reproductive performance were not affected in studies with male rats given oral doses of losartan potassium up to approximately 150 mg/kg/day. The administration of toxic dosage levels in females (300/200 mg/kg/day) was associated with a significant decrease in the number of corpora lutea/female, implants/female, and live fetuses/female at C-section. At 100 mg/kg/day only a decrease in the number of corpora lutea/female was observed. The relationship of these findings to drug treatment is uncertain since there was no effect at these dosage levels on implants/pregnant female, percent post-implantation

loss, or live animals/litter at parturition. In non-pregnant rats dosed at 135 mg/kg/day for 7 days, systemic exposure (AUCs) for losartan and its active metabolite were approximately 66 and 26 times the exposure achieved in man at the maximum recommended human daily dosage (100 mg).
Teratogenicity: Losartan potassium has been shown to produce adverse effects in rat fetuses and neonates, including decreased body weight, delayed physical and behavioral development, mortality and renal toxicity. With the exception of neonatal weight gain (which was affected at doses as low as 10 mg/kg/day), doses associated with these effects exceeded 25 mg/kg/day (approximately three times the maximum recommended human dose of 100 mg on a mg/m2 basis). These findings are attributed to drug exposure in late gestation and during lactation. Significant levels of losartan and its active metabolite were shown to be present in rat fetal plasma during late gestation and in rat milk.

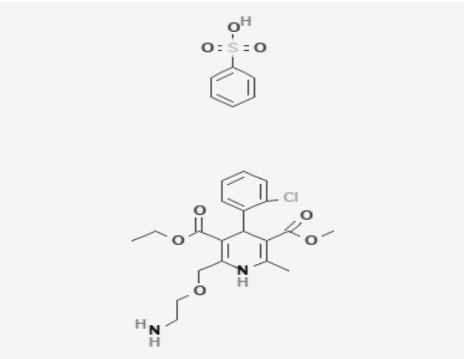
7. Description

ANGICAM-LT Tablets are yellow coloured, biconvex, film coated tablets plain on both the sides.

ANGICAM-LT Tablets contains 5 mg of amlodipine and 50 mg of losartan potassium for oral administration in adults.

Amlodipine Besylate

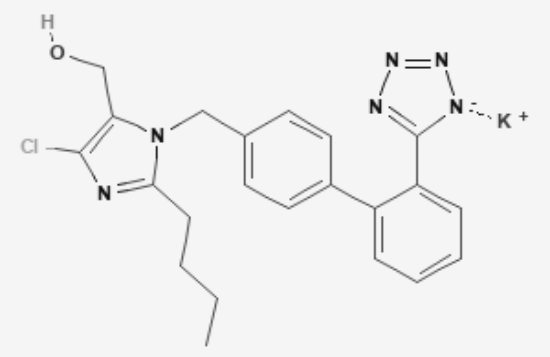
Amlodipine besylate is the besylate salt of amlodipine. Amlodipine is a long-acting calcium channel blocker (CCB) of a synthetic dihydropyridine class with antihypertensive and antianginal effects. Amlodipine besylate is a white crystalline powder.
Molecular Weight: 567.1 g/mol.
Molecular Formula: C20H25ClN2O5•C6H6O3S.
Chemical Name: 3-Ethyl-5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(2- chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulphonate.
Structural Formula:



Losartan Potassium

Losartan Potassium is the potassium salt of losartan, a non-peptide angiotensin II receptor antagonist with antihypertensive activity.
Losartan potassium is a white to off-white powder.

Molecular Weight: 461 g/mol.
Molecular Formula: C22H22ClKN6O.
Chemical Name: potassium;[2-butyl-5-chloro-3-[[4-[2-(1,2,3-triaza-4-azanidacyclopenta-2,5-dien-5-yl)phenyl]phenyl]methyl]imidazol-4-yl]methanol.
Structural Formula:



Inactive ingredients (excipients) of ANGICAM-LT Tablets contain Microcrystalline Cellulose, Lactose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Magnesium Stearate, Instacoat Aqua III (Yellow), and Purified Water.

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2Shelf-life

24 months.

8.3Packaging Information

Strip of 15 tablets.

8.4Storage and Handling Instructions

Store protected from light and moisture at a temperature not exceeding 30°C.
Keep out of reach of children.

9. Patient Counseling Information

Instructions to Patients

- Instruct patients to take this medicine exactly as prescribed by your doctor. Do not change the dose or stop therapy without consulting doctor.
- Patients are advised to take ANGICAM-LT Tablets 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 at a time.

- If patients miss a dose, they can take it as soon as they remember. Do not take ANGICAM-LT Tablets if it has been more than 12 hours since the last missed dose. Wait and take the next dose at regular scheduled time.
- It is advised to strictly avoid this medicine during pregnancy and lactation.
- Use of this medicine is not recommended in children.
- Patients should be informed that while taking ANGICAM-LT Tablets do not stop taking other prescription medicines, including any other blood pressure medicines, without consulting their doctor.

10. Details of Manufacturer

Mepromax Lifesciences Pvt. Ltd.
16- Pharmacity, Selaqui, Dehradun – 248 011, Uttarakhand.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : 23/UA/2007; Date of FDA Product Permission: 01/03/2007.

12. Date of Revision

February 2023.

Marketed by:
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.