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 Atenolol Tablets
(Brand Name: ANGICAM®-BETA Tablets)

2. Qualitative and Quantitative Composition

Each uncoated tablet contains:
Amlodipine Besylate IP equivalent to Amlodipine …… 5 mg.
Atenolol IP …… 50 mg.
Excipients ……. q.s.

3. Dosage Form and Strength

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

4. Clinical Particulars

4.1 Therapeutic Indication

ANGICAM-BETA Tablets are indicated in the treatment of mild to moderate hypertension in adult patients whose blood pressure is not adequately controlled by monotherapy.

4.2Posology and Method of Administration

For oral administration.
Adults: 1 tablet to be administered once daily with or without food.
Amlodipine is effective in doses between 2.5 mg to 10 mg once daily.
Atenolol is effective in doses between 25 mg to 100 mg once daily.
Or, as directed by the physician.

4.3Contraindications

ANGICAM-BETA Tablets are contraindicated in patients with:

- Hypersensitivity to amlodipine or to atenolol or to any component of the formulation.
- Cardiogenic shock.
- Unstable angina.
- Significant aortic stenosis.
- Sinus bradycardia.

- Heart block greater than first degree.
- Overt cardiac failure.
- Severe hypotension.
- Acute porphyria.

4.4Special Warnings and Precautions for Use

Amlodipine

Hypotension: Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. Because of the gradual onset of action, acute hypotension is unlikely.

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

Patients with Hepatic Failure: Amlodipine is extensively metabolized by the liver and the plasma elimination half-life (t½) is 56 hours in patients with impaired hepatic function. Thus, caution should be exercised and dose should be titrated slowly in patients with severe hepatic impairment.

Atenolol

Cardiac Failure: Sympathetic stimulation is necessary in supporting circulatory function in congestive heart failure, and beta-blockade carries the potential hazard of further depressing myocardial contractility and precipitating severe failure. In patients with acute myocardial infarction, cardiac failure which is not promptly and effectively controlled by 80 mg of intravenous furosemide or equivalent therapy is a contraindication to beta-blocker treatment.

Risk of New Onset Cardiac Failure: Continued depression of the myocardium with beta-blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, patients should be treated appropriately according to currently recommended guidelines, and the response observed closely. If cardiac failure continues despite adequate treatment, atenolol should be withdrawn.

Cessation of Therapy: Patients with coronary artery disease, who are being treated with atenolol, should be advised against abrupt discontinuation of therapy. Severe exacerbation of angina and the occurrence of myocardial infarction and ventricular arrhythmias have been reported in angina patients following the abrupt discontinuation of therapy with beta-blockers. These complications may occur with or without preceding exacerbation of the angina pectoris. As with other beta-blockers, when discontinuation of atenolol is planned, the patients should be carefully observed and advised to limit physical activity to a minimum. If the angina worsens or acute coronary insufficiency develops, it is recommended that atenolol be promptly reinstituted, at least temporarily. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue atenolol therapy abruptly even in patients treated only for hypertension.

Concomitant Use of Calcium Channel Blockers: Bradycardia and heart block can occur and the left ventricular end diastolic pressure can rise when beta-blockers are administered with verapamil

or diltiazem. Patients with preexisting conduction abnormalities or left ventricular dysfunction are particularly susceptible.

Bronchospastic Diseases: Patients with bronchospastic disease should, in general, not receive beta-blockers. Because of its relative beta-1 selectivity, however, atenolol may be used with caution in patients with bronchospastic disease who do not respond to, or cannot tolerate, other antihypertensive treatment. Since beta-1 selectivity is not absolute, the lowest possible dose of atenolol should be used with therapy initiated at 50 mg and a beta-2 stimulating agent (bronchodilator) should be made available. If dosage must be increased, dividing the dose should be considered in order to achieve lower peak blood levels.

Major Surgery: Chronically administered beta-blocking therapy should not be routinely withdrawn prior to major surgery; however, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Diabetes and Hypoglycemia: Atenolol should be used with caution in diabetic patients if a beta-blocking agent is required. Beta-blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected. At recommended doses, atenolol does not potentiate insulin-induced hypoglycemia and, unlike non-selective beta-blockers, does not delay recovery of blood glucose to normal levels.

Thyrotoxicosis: Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. Abrupt withdrawal of beta-blockade might precipitate a thyroid storm; therefore, atenolol therapy to be withdrawn in patients suspected of developing thyrotoxicosis.

Untreated Pheochromocytoma: Atenolol should not be given to patients with untreated pheochromocytoma.

Allergic Reactions: While taking beta-blockers, patients with a history of anaphylactic reactions to a variety of allergens may have a more severe reaction on repeated challenge (either accidental, diagnostic or therapeutic). Such patients may be unresponsive to the usual doses of epinephrine used to treat the allergic reaction.

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.

Atenolol

Catecholamine-Depleting Drugs (E.g., Reserpine): When these drugs are given with beta-blocking agents, they may cause an additive effect. Patients treated with atenolol plus a catecholamine depletory should therefore be closely observed for evidence of hypotension and/or marked bradycardia which may produce vertigo, syncope, or postural hypotension.

Calcium Channel Blockers: Concomitant use of beta-blockers with atenolol may produce an additive effect.

Amiodarone (Antiarrhythmic Agent): When amiodarone is given concomitantly with atenolol, it may produce an additive effect.

Disopyramide: Disopyramide is a Type I antiarrhythmic drug with potent negative inotropic and chronotropic effects. Disopyramide has been associated with severe bradycardia, asystole and heart failure when administered with beta-blockers.

Clonidine: Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. If the two drugs are co-administered, the beta-blocker should be withdrawn several days before the gradual withdrawal of clonidine. If replacing clonidine by beta-blocker therapy, the introduction of beta-blockers should be delayed for several days after clonidine administration has stopped.

Indomethacin (Prostaglandin Synthase Inhibiting Drugs): Concomitant use of these drugs with atenolol may decrease the hypotensive effects of beta-blockers.

Digitalis: Both cardiac glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

4.6Use in Special Populations

Pregnant Women

Amlodipine: Pregnancy Category C; Atenolol: Pregnancy Category D. There are no adequate and well-controlled studies in pregnant women. In animal studies, reproductive toxicity was observed at high doses of amlodipine. Atenolol can cause fetal harm when administered to a pregnant woman. Atenolol crosses the placental barrier and appears in cord blood. Beta-blockers, in general, have been associated with a decrease in placental perfusion which may result in intra-uterine deaths, immature and premature deliveries. Administration of atenolol to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation. Thus, ANGICAM-BETA Tablets are not recommended for use during pregnancy.

Lactating Women

Limited available data from a published clinical study reports that amlodipine is present in human milk. However, no adverse effects of amlodipine on the breastfed infant have been observed. There is significant accumulation of atenolol in breast milk. Neonates born to mothers who are receiving atenolol at parturition or breast-feeding may be at risk for hypoglycemia and bradycardia. Because of the potential for 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 effectiveness of this combination product in paediatric patients have not been established. Thus, ANGICAM-BETA Tablets are not recommended for use in children.

Geriatric Patients

Dosage requirements may be reduced, especially in patients with impaired renal function. In general, elderly patients present higher atenolol plasma levels with total clearance values about 50% lower than younger subjects. The half-life is markedly longer in the elderly compared to younger subjects. Thus, a lower initial dose is recommended in elderly patients.

Renal Impairment Patients

Amlodipine may be given in normal dosage in patient with renal impairment. However, excretion of atenolol is correlated with renal function and is prolonged in patients with renal impairment. Since atenolol is significantly excreted via the kidneys, the dosage should be adjusted in cases of severe impairment of renal function.

Hepatic Impairment Patients

There is no significant hepatic metabolism of atenolol. But, amlodipine is extensively metabolized by the liver and the plasma elimination half-life increases in patients with impaired hepatic function. Thus, slow dose titration and careful monitoring may be required in patients with severe hepatic impairment.

4.7Effect on Ability to Drive and Use Machines

Atenolol use is unlikely to result in any impairment of the ability of patients to drive or operate machinery. However, amlodipine can have minor or moderate influence on the ability to drive and use machines. If patients taking this medicine suffer from dizziness, headache, fatigue or nausea the ability to react may be impaired. Caution is recommended especially at the start of treatment.

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 System: 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 Disorders: 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.

Atenolol

Atenolol is well tolerated. Most adverse effects have been mild and transient in nature. In clinical studies, the undesired events reported are usually attributable to the pharmacological actions of atenolol.

The following undesired events, listed by body system, have been reported with the following frequencies: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Blood and Lymphatic System: Rare: Purpura, thrombocytopenia, leucopenia.

Psychiatric Disorders: Uncommon: Sleep disturbance. Rare: Mood changes, depression, anxiety, nightmares, confusion, psychoses and hallucinations.

Nervous System: Rare: Dizziness, headache, paraesthesia of extremities.

Eye Disorders: Rare: Dry eyes, impaired vision, visual disturbances.

Cardiac: Common: Bradycardia. Rare: Heart failure deterioration, precipitation of heart block.
Vascular: Common: Cold extremities. Rare: Postural hypotension, which may be associated with syncope; intermittent claudication, may be increased if already present in patients Raynaud's phenomenon.
Respiratory, Thoracic and Mediastinal Disorders: Rare: Bronchospasm may occur in patients with bronchial asthma or a history of asthmatic complaints.
Gastrointestinal: Common: Gastrointestinal disturbances, constipation. Rare: Dry mouth.
Hepato-Biliary: Uncommon: Elevations of transaminase levels. Rare: Hepatic toxicity including intrahepatic cholestasis.
Skin and Subcutaneous Tissue: Rare: Alopecia, psoriasiform skin reactions, exacerbation of psoriasis, skin rashes. Not known: Hypersensitivity reactions, including angioedema and urticaria.
Musculoskeletal and Connective Tissue: Not known: Lupus like syndrome.
Reproductive System: Rare: Impotence.
General: Common: Fatigue, sweating.
Investigations: Very Rare: An increase in antinuclear antibodies (ANA) has been observed. However, the clinical relevance of this is not clear.

4.9Overdose

Amlodipine

Overdose might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly 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 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.

Atenolol

The predominant symptoms reported following atenolol overdose are lethargy, impaired respiratory drive, wheezing, sinus pause and bradycardia. Additionally, common effects associated with overdose of any beta-adrenergic blocking agent and which might also be expected in atenolol overdose are congestive heart failure, heart block (second or third degree), hypotension, bronchospasm and/or hypoglycemia.

Treatment of overdose should be directed to the removal of any unabsorbed drug by induced emesis, gastric lavage, or administration of activated charcoal. Atenolol can be removed from the general circulation by hemodialysis. Other treatment modalities should be employed at the physician's discretion and may include:

- Bradycardia: Intravenous atropine. If there is no response to vagal blockade, give isoproterenol cautiously. In refractory cases, a transvenous cardiac pacemaker may be indicated.
- Heart block (second or third degree): Isoproterenol or transvenous cardiac pacemaker.
- Cardiac failure: Digitalize the patient and administer a diuretic. Glucagon has been reported to be useful.
- Hypotension: Vasopressors such as dopamine or norepinephrine (levarterenol). Monitor blood pressure continuously.
- Bronchospasm: A beta-2 stimulant such as isoproterenol or terbutaline and/or aminophylline.
- Hypoglycemia: Intravenous glucose.

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.

Atenolol

Atenolol is a beta-1 selective (cardioselective) beta-adrenergic receptor blocking agent without membrane stabilizing or intrinsic sympathomimetic (partial agonist) activities. This preferential effect is not absolute, however, and at higher doses, atenolol inhibits beta-2 adrenoreceptors, chiefly located in the bronchial and vascular musculature.

The mechanisms of the antihypertensive effects of beta-blocking agents have not been fully understood. Several possible mechanisms have been proposed and include:

- Competitive antagonism of catecholamines at peripheral (especially cardiac) adrenergic neuron sites, leading to decreased cardiac output,
- A central effect leading to reduced sympathetic outflow to the periphery, and
- Suppression of renin activity.

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.

Atenolol

In standard animal or human pharmacological tests, beta-adrenoreceptor blocking activity of atenolol has been demonstrated by:

- Reduction in resting and exercise heart rate and cardiac output
- Reduction of systolic and diastolic blood pressure at rest and on exercise
- Inhibition of isoproterenol-induced tachycardia
- Reduction in reflex orthostatic tachycardia

Following an oral dose of 50 mg, both beta-blocking and antihypertensive effects persist for at least 24 hours.

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.

Atenolol

Absorption: Absorption of an oral dose of atenolol is rapid, but incomplete. Approximately 50% of an oral dose is absorbed from the gastrointestinal tract, the remainder being excreted unchanged in the feces. Peak blood levels are reached between 2 to 4 hours after ingestion.

Distribution: Only a small amount (6 to 16%) of atenolol is bound to plasma proteins. Atenolol penetrates tissues poorly due to its low lipid solubility. The volume of distribution is 50 to 75 litres. This kinetic profile results in relatively consistent plasma drug levels with about a four-fold inter-patient variation.

Metabolism: Atenolol undergoes little or no metabolism by the liver.
Excretion: Atenolol is eliminated primarily by renal route. Most of an absorbed dose (85 to 100%) is excreted unchanged via the urine. The elimination half-life of oral atenolol is approximately 6 to 7 hours, and there is no alteration of the kinetic profile of the drug by chronic administration. When renal function is impaired, elimination of atenolol is closely related to the glomerular filtration rate; significant accumulation occurs when the creatinine clearance falls below 35 ml/min/1.73m^2.

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.

Atenolol

Toxicity: Chronic studies employing oral atenolol performed in animals have revealed the occurrence of vacuolation of epithelial cells of Brunner's glands in the duodenum of both male and female dogs at all tested dose levels of atenolol (starting at 15 mg/kg/day or 7.5 times the maximum recommended [100 mg/day] human antihypertensive dose) and increased incidence of atrial degeneration of hearts of male rats at 300 but not 150 mg atenolol/kg/day (150 and 75 times the maximum recommended human antihypertensive dose, respectively).
Carcinogenesis: Two long-term (maximum dosing duration of 18 or 24 months) rat studies and one long-term (maximum dosing duration of 18 months) mouse study, each employing dose levels as high as 300 mg/kg/day or 150 times the maximum recommended human antihypertensive dose

i.e., 100 mg/day, did not indicate a carcinogenic potential of atenolol. A third (24 month) rat study, employing doses of 500 and 1,500 mg/kg/day (250 and 750 times the maximum recommended human antihypertensive dose) resulted in increased incidences of benign adrenal medullary tumors in males and females, mammary fibroadenomas in females, and anterior pituitary adenomas and thyroid parafollicular cell carcinomas in males.

Mutagenesis: No evidence of a mutagenic potential of atenolol was uncovered in the dominant lethal test (mouse), *in vivo* cytogenetics test (Chinese hamster) or Ames test (S typhimurium).

Impairment of Fertility: Fertility of male or female rats (evaluated at dose levels as high as 200 mg/kg/day or 100 times the maximum recommended human dose) was unaffected by atenolol administration.

7. Description

ANGICAM-BETA Tablets are off-white, circular, flat, beveled, uncoated tablet with breakline between A and B, and engraved on one side and plain on other side.

ANGICAM-BETA Tablets contains 5 mg of amlodipine and 50 mg of atenolol for oral administration in adults.

Amlodipine Besylate

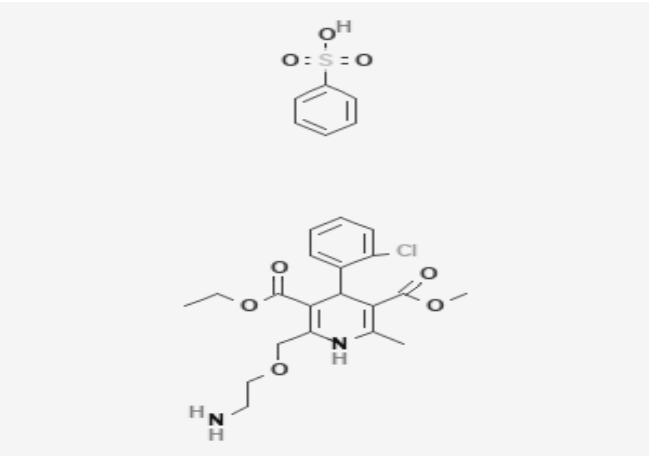
Amlodipine besylate is the besylate salt of amlodipine. Amlodipine is a long-acting calcium channel blocker (CCB) of a synthetic dihydropyridine class with antihypertensive and antianginal effects. Amlodipine besylate is a white crystalline powder.

Molecular Weight: 567.1 g/mol.

Molecular Formula: C20H25CIN2O5•C6H6O3S.

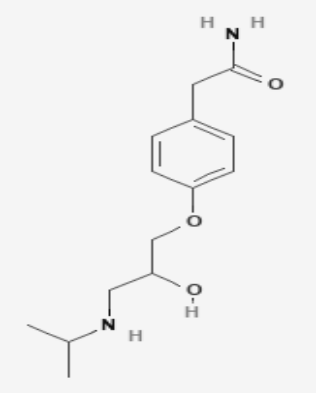
Chemical Name: 3-Ethyl-5-methyl (±)-2-[(2-aminoethoxy)methyl]-4-(2- chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulphonate.

Structural Formula:



Atenolol

Atenolol is a synthetic isopropylamino-propanol derivative used in the treatment of hypertension and angina pectoris. Atenolol acts as a peripheral, cardioselective beta blocker specific for beta-1 adrenergic receptors.
Atenolol is a white, crystalline powder.
Molecular Weight: 266.34 g/mol.
Molecular Formula: C14H22N2O3.
Chemical Name: 2-[4-[2-hydroxy-3-(propan-2-ylamino)propoxy]phenyl]acetamide.
Structural Formula:



Inactive ingredients (excipients) of ANGICAM-BETA Tablets contain Dibasic Calcium Phosphate, HPMC Methocel, Isopropyl Alcohol, Methylene Chloride, Talc, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate, and Colloidal Silicon Dioxide.

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 25°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.
- Instruct patients to take ANGICAM-BETA 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-BETA 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 avoid this medicine during pregnancy and lactation.
- Use of this medicine is not recommended in children.
- Patients should be informed that while taking ANGICAM-BETA Tablets do not stop taking other prescription medicines, including any other blood pressure medicines, without consulting their doctor.

10. Details of Manufacturer

Blue Cross Laboratories Pvt. Ltd.
A – 12, MIDC, Ambad, Nashik – 422 010 Maharashtra.

11. Details of Permission or License Number with Date

Mfg. Lic. No. : BD/25; Date of FDA Product Permission: 03/02/2004.

12. Date of Revision

April 2021.

MADE IN INDIA 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.