GIS Pharma Part. Ltd.
ห้างหุ้นส่วนจำกัด จีไอเอส ฟาร์มา

AMCARDIA-10
Amlodipine Tablets 10 mg

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โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

ฆศ.842/2561

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COMPOSITION :

Each uncoated tablet contains :

Amlodipine Besilate BP equivalent to Amlodipine 10 mg. Amlodipine Besilate, a basic dihydropyridine derivative, is a long acting calcium channel blocker.

PHARMACOLOGY :

Amlodipine inhibits the "slow" calcium channel in the cardiac and vascular smooth muscle. Its main site of action is the peripheral vasculature though it also produces vasodilation in coronary vascular beds.

In patients with mild to moderate essential hypertension, Amlodipine has a sustained and gradual onset of antihypertensive effect. Once daily dosage regimen of 2.5 to 10 mg produces reduction in mean systolic and diastolic blood pressure of about 10 to 18% in most studies.

Amlodipine reduces the afterload by decreasing the peripheral vascular resistance and increases the cardiac output. In addition to its ability to reduce afterload, amlodipine increases myocardial oxygen supply, reduces demand and improves exercise capacity in patients with symptomatic myocardial ischaemia.

PHARMACOKINETICS :

Amlodipine is slowly but almost completely absorbed after oral administration and the peak levels are attained between 6-12 hours. The bioavailability of amlodipine is about 64-80% and is not influenced by food.

Amlodipine is extensively and slowly metabolized by the liver and none of the amlodipine metabolites have significant pharmacological activity.

Amlodipine has relatively long elimination half-life of 35-45 hours permitting a once-daily administration. In patients with hepatic cirrhosis and in the elderly, amlodipine elimination is significantly reduced and some degree of accumulation is noted and relevant dosage adjustments should be made.

INDICATIONS :

Hypertension : Several studies have demonstrated the efficacy of amlodipine administered once daily in mild to moderate essential hypertension. Importantly, ambulatory blood pressure monitoring has shown that amlodipine reduces blood pressure throughout a 24 hour period.

Chronic stable angina : Amlodipine improves both subjective symptoms and objective symptoms of chronic stable angina. It can be used with other antianginal drugs.

Vasospastic angina : Amlodipine reduces symptoms of Vasospastic angina.

Amlodipine in the above condition may be used as monotherapy or with other drugs.

CONTRAINDICATIONS :

Amlodipine is contraindicated in patients with known sensitivity to Amlodipine, dihydropyridines or other ingredients in the formula.

WARNING :

Increase Angina and / or Myocardial infarction : Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated.

PRECAUTIONS :

General : Since the vasodilation induced by Amlodipine is gradual in onset, acute hypotension has rarely been reported after oral administration of Amlodipine. Nonetheless, caution should be exercised when administering. Amlodipine as with any other peripheral vasodilator particularly in patients with

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severe aortic stenosis.

Special Warnings and Special Precautions for Use

Use in Patients with Heart Failure

In a, long-term, placebo controlled study (PRAISE - 2) of amlodipine in patients with NYHA lll and IV heart failure of nonischemic etiology, amlodipine was associated with significantly increase reports of pulmonary edema despite no significant difference in the incidence of worsening heart failure as compared to placebo

Use in Patients with Impaired Hepatic function

As with all calcium antagonists, amlodipine half-life is prolonged in patients with impaired liver function and dosage recommendations have not been established. The drug should therefore be administered with caution in these patients.

Pregnancy : There are no adequate and well-controlled studies in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers : It is not known whether Amlodipine is excreted in human milk.

In the absence of this information, it is recommended that nursing be discontinued while Amlodipine is administered.

Paediatric Use : Safety and effectiveness of Amlodipine in children has not been established.

INTERACTION WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION :

Amlodipine has been saftly administered with thiazide diuretics, alpha blockers, beta blockers,

angiotensin-converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerine, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.

In vitro data from studies with human plasma indicate that amlodipine has no effect on protein binding of the drugs tested (digoxin, phenytoin, warfarin, of indomethacin).

Special Studies: Effect of other agents on amlodipine

CIMETIDINE : Co-administration of amlodipine with cimetidine did not alter the pharmacokinetics of amlodipine.

GRAPEFRUIT JUICE : Co-administration of 240 ml of grapefruit juice with a single oral dose of amlodipine 10 mg in 20 healthy volunteers had no significant effect on the phamcokinetics of amlodipine.

ALUMINUM/ MAGNESIUM (antacid) : Co-administration of an aluminum/magnesium antacid with a single dose of amlodipine had no significant effect on the pharmacokinetics of amlodipine.

SILDENAFIL : A single 100 mg dose of sildenafil in subjects with essential hypertension had no effect on the pharmacokinetics parameters of amlodipine. When amlodipine and sildenafil were used in combination, each agent independently exerted its own blood pressure lowering effect.

Special studies : Effect of amlodipine on other agents.

ATORVASTATIN : Co-Administration of multiple 10 mg doses of amlodipine with 80 mg of atorvastatin resulted in no significant change in the steady state phamcokinetics parameters of atorvastatin.

DIGOXIN : Co-administration of amlodipine with digoxin did not change serum digoxin levels of digoxin renal clearance in normal volunteers.

ETHANOL (alcohol) : Single and multiple 10 mg doses of amlodipine had no significant effect on the phamacokinetics of ethanol.

WARFARIN : Co-administration of amlodipine with warfarin did not change the warfarin prothrombin response time.

CYCLOSPORIN : Pharmacokinetics studies with cyclosporin have demonstrated that amlodipine does not significant alter the pharmacokinetics of cyclosporin.

Drug/Laboratory Test Interaction : None known.

UNDESIRABLE EFFECTS :

Amlodipine is well tolerated. In placebo controlled clinical

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trials involving patients with hypertension or angina, the most commonly observed side effects were :

Autonomic Nervous System : flushing

Body As A Whole : fatigue

Cardiovascular, General : edema

Central & Peripheral Nervous System : dizziness, headache

Gastrointestinal : abdominal pain, nausea

Heart Rate/ Rhythm : palpitations

Psychiatric : somnolence

In these clinical trials no pattern of clinically significant laboratory test abnormalities related to amlodipine has been observed.

Less commonly observed side effects in marketing experience include:

Autonomic Nervous : dry mouth, increased sweating

Body As A Whole : asthenia, back pain, malaise, pain, weight increase/ decrease

Cardiovascular, General: hypotension, syncope

Central & Peripheral Nervous: hypertonia, hypoesthesia/ paresthesia, peripheral neuropathy, tremor

Endocrine : gynecomastia

Gastrointestinal : altered bowel habits, dyspepsia (including gastritis), gingival hyperplasia, pancreatitis, vomiting

Metabolic/ Nutritional : hyperglycemia

Masculoskeletal : arthralgia, muscle cramps, myalgia

Platelet/ Bleeding/ Clotting: purpura, thrombocytopenia

Psychiatric: impotence, insomnia, mood changes

Respiratory: coughing, dyspnea, rhinitis

Skin/ Appendages : alopecia, skin discoloration, urticaria

Special senses: taste perversion tinnitus

Urinary: increased urinary frequency, micturition disorder, nocturia

Vascular (Extracardiac) : vasculitis

Vision : visual disturbances

White Blood Cell/ R.E.S. : leucopenia

Rarely, allergic reation including pruritus, rash, angioedema, and erythema multiforme.

of amlodipine. In many instances, causal association is uncertain.

As with other calcium channel blockers the following adverse events have been rarely reported and cannot be distinguished from the natural history of the underlying disease: myocardial infarction, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation) and chest pain.

OVERDOSE :

Available data suggest that gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and probably prolonged systemic hypotension up to and including shock with fatal outcome have been reported.

Administration of activated charcoal to healthy volunteers immediately or up to two hours after ingestion of amlodipine 10 mg has been shown to significant decrease amlodipine absorption. Gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to amlodipine overdosage calls for active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities, and attention to circulation fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone and blood pressure, provided that there is no contraindication to its use. Intravenous calcium gluconate may be beneficial in reversing the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

DOSAGE AND ADMINISTRATION :

The usual initial antihypertensive oral dose of Amlodipine is 5 mg once daily with a maximum dose of 10 mg once daily. The recommended dose for chronic stable or vasospastic angina is 5-10 mg with a lower dose of 2.5 mg is suggested in

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the elderly and in patients with hepatic insufficiency. Most patients will require 10 mg for adequate effect.

PRESENTATION :

Blister Strip of 10 tablets (10 X 10's).

STORAGE :

Store below 30°C in a dry place. Protect from light.

KEEP OUT OF REACH OF CHILDRE.

MANUFACTURED BY :

UNIQUE PHARMACEUTICAL LABORATORIES

(A Div. of J.B. Chemicals & Pharmaceuticals Ltd.)

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