Sidopin®

Amlodipine Tablet

DESCRIPTION

Sidopin® is a preparation of amlodipine. Amlodipine is a calcium antagonist (calcium blocker, calcium slow channel blocker) of the dihydropyridine group and inhibits the transmembrane influx of calcium ions into cardiac and smooth muscle. The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle.

INDICATIONS

Sidopin® is indicated for the first-line treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. Patients not adequately controlled on a single antihypertensive agent may benefit from the addition of **Sidopin®** which has been used in combination with a thiazide diuretic, beta-adrenoceptor blocking agent or an angiotensin converting enzyme inhibitor.

Sidopin® is indicated for the first-line treatment of myocardial ischaemia, whether due to fixed obstruction (stable angina) and/or vasospasm/vasoconstriction (Prinzmetal's or variant angina) of the coronary vasculature. Amlodipine may also be used where the clinical presentation suggests a possible vasospastic/vasoconstrictive component but where vasospasm/vasconstriction has not been confirmed. Amlodipine may be used as monotherapy or in combination with other antianginal drugs in patients with angina that is refractory to nitrates and/or adequate doses of beta-adrenoceptor blocking agents.

DOSAGE AND ADMINISTRATION

Adults : For both hypertension and angina, the recommended initial dose is 5 mg **Sidopin®** orally once daily which may be increased to a maximum dose of 10 mg depending on the individual patient's response.

The dose does not need adjusting when **Sidopin®** is given concurrently with thiazide diuretics, beta-adrenoceptor blocking agents or angiotensin-converting enzyme inhibitors. **Sidopin®** can be administered with or without food.

Use in children : Since there is no clinical experience in patients of less than 18 years, use in children is not currently recommended.

Use in the elderly : Although elderly patients may have higher plasma concentrations of **Sidopin®** than younger patients, the terminal elimination half-lives are similar. **Sidopin®** is similarly well-tolerated in elderly or younger patients. Therefore the normal dosage is recommended.

Use with renal impairment : Amlodipine is extensively metabolised to inactive metabolites with 10% excreted as unchanged drug in the urine. Changes in amlodipine plasma concentration are not correlated with the degree of renal impairment, therefore the normal dosage is recommended. Amlodipine is not dialysable.

Use in patients with impaired hepatic function : The half-life of amlodipine is prolonged in patients with impaired liver function and dosage recommendations have not been established. Amlodipine should therefore be administered with caution in these patients.

CONTRA-INDICATIONS, WARNINGS, ETC.

Contra-indications:

Amlodipine is contra-indicated in patients with a known sensitivity to dihydropyridines (e.g. Nifedipine, Nicardipine, Isradipine).

Warnings and precautions:

Use during pregnancy and lactation : Although some dihydropyridine compounds have been found to be teratogenic in animals, data in the rat and rabbit for amlodipine provide no evidence for a teratogenic effect. There is, however no clinical experience with amlodipine in pregnancy or lactation. Accordingly, amlodipine should not be administered during pregnancy or lactation or to women of child-bearing potential unless effective contraception is used.

Driving/use of machinery:

Clinical experience with amlodipine indicates that it is unlikely to impair a patient's ability to drive or use machinery.

DRUG INTERACTIONS

Amlodipine has been safely administered with thiazide diuretics, beta-adrenoceptor blocking drugs, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual glyceryl trinitrate, non-steroidal anti-inflammatory drugs, antibiotics and oral hypoglycaemic agents.

Co-administration of amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers. Co-administration of cimetidine did not alter the pharmacokinetics of amlodipine.

In healthy volunteers, co-administration of amlodipine did not significantly alter the effect of warfarin on prothrombin time. The introduction of amlodipine is not likely to result in the need for modification of an established warfarin regimen.

In vitro data from studies with human plasma indicates that amlodipine has no effect on protein binding of digoxin, phenytoin, warfarin or indomethacin.

SIDE-EFFECTS

Amlodipine is well tolerated. In placebo controlled clinical trials involving patients with hypertension or angina, the most commonly observed side-effects were headache, oedema, fatigue, nausea, flushing and dizziness. No clinically significant pattern of laboratory test abnormalities related to amlodipine has been observed.

OVERDOSAGE

There is no well documented experience with amlodipine overdosage. Since amlodipine absorption is slow, gastric lavage may be worthwhile in some cases. Clinically significant hypotension due to amlodipine overdosage calls for active cardiovascular support including monitoring of cardiac and respiratory function, elevation of extremities and attention to circulating fluid volume and urine output. A vasoconstrictor agent may be helpful in restoring vascular tone and blood pressure, provided that there is no contra-indication to its use. Since amlodipine is highly protein-bound, dialysis is unlikely to be of benefit.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Sidopin® 5 tablet : Box containing 2/5 strips of 10 tablets each. Each tablet contains amlodipine besilate BP equivalent to 5 mg amlodipine.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

® REGD. TRADEMARK

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