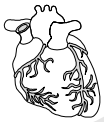

Camlodin®

Amlodipine

Calcium Antagonist

COMPOSITION

Camlodin® 5 mg tablet : Each tablet contains 5 mg Amlodipine BP as the besylate salt.

Camlodin® 10 mg tablet : Each tablet contains 10 mg Amlodipine BP as the besylate salt.

PHARMACOLOGY

Camlodin® (Amlodipine) is a calcium antagonist of the dihydropyridine group and inhibits the transmembrane influx of calcium ion into cardiac & smooth muscle. It is used for the treatment of hypertension and angina pectoris.

Camlodin® is slowly and incompletely absorbed, with 60-80% of an oral dose reaching the systemic circulation. Plasma half life ranges from 30-60 hrs (mean 35.7 hrs). Camlodin® is extensively metabolized in the liver prior to excretion with only about 5% unchanged drug excreted in the urine.

INDICATION

1. *Hypertension*:

   Camlodin® is indicated for the first line treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

2. *Chronic Stable Angina*:

   Camlodin® is indicated for the treatment of stable angina.
   Camlodin® may be used alone or in combination with other antianginal agents.

3. *Vasospastic Angina*:

   Camlodin® is indicated for the treatment of confirmed or suspected vasospastic angina. Camlodin® may be used as monotherapy or in combination with other antianginal drugs.

DOSAGE AND ADMINISTRATION

The usual initial antihypertensive oral dose of Camlodin® is 5 mg once daily with a maximum dose of 10 mg once daily. Small, fragile or elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily dose and this dose may be used when adding Camlodin® to other antihypertensive therapy.
Dosage should be adjusted according to each patient's need.

The recommended dose for stable or vasospastic chronic angina is 5-10 mg, with the lower dose suggested in the elderly and in patients with hepatic insufficiency. Most patients will require 10 mg for adequate effect.

CONTRAINDICATION AND PRECAUTION

Camlodin® is contraindicated in patients with known hypersensitivity to dihydropyridine (e.g. amlodipine, nifedipine, nicardipine, isradipine).

Since the vasodilatation 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 with any other peripheral vasodilator particularly in patients with severe aortic stenosis.

*Use in patients with congestive heart failure***:**
Although haemodynamic studies and a controlled in class II-III heart failure patients have shown that amlodipine did not lead to clinical deterioration as measured by exercise tolerance, left ventricular ejection fraction and clinical symptomatology in general, all calcium channel blockers should be used with caution in patients with heart failure.

*Beta-blocker withdrawal***:**
Camlodin® is not a beta-blocker and therefore gives no protection against the danger of abrupt beta-blocker withdrawal; any such withdrawal should be gradual reduction of the dose of beta-blocker.

*Patients with hepatic failure***:**
Since Camlodin® is extensively metabolised by the liver & plasma elimination half life is 56 hours in patients with impaired hepatic function , so caution should be exercised when administering Camlodin® to patients with hepatic impairment.

SIDE EFFECT

Camlodin® is well tolerated. Headache, oedema, fatigue, nausea, flushing, dizziness, gum hyperplasia; erythema multiforme are reported.

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension & possibly a reflux tachycardia.

In human, experience with intentional over dosage of amlodipine is limited. If massive over dosage occurs , active cardiac and respiratory monitoring should be instituted . Frequent blood pressure measurements are essential.

Camlodin®

DRUG INTERACTION

Digoxin: Absence of any interaction between amlodipine and digoxin in healthy volunteers has been documented in a controlled clinical study.

Warfarin: An unpublished study in healthy volunteers indicates that amlodipine does not significantly alter the effect of warfarin on prothrombin time.

Cimetidine: An unpublished clinical study indicated no interaction between amlodipine & cimetidine in healthy volunteers.

Food: Food does not alter the rate or extent of absorption of amlodipine.

USE IN PREGNANCY AND LACTATION

Pregnancy: No data are available at the present time. Therefore amlodipine should not be prescribed in women known to be pregnant.
Lactation: No data are available at the present time, so it is probably best for breast-feeding mothers to avoid the drug.

STORAGE CONDITION

Keep medicine out of reach of children. Store in a cool and dry place.

HOW SUPPLIED

Camlodin® 5 tablet : Box containing 5 x 6 tablets in blister pack.
Camlodin® 10 tablet : Box containing 3 x 10 tablets in blister pack.