Varinil® (Tablets)

1149
Ref. No.:INS149/04.18

Amlodipine Besylate
Calcium - channel blocker
Antihypertensive

VARINIL® TABLETS 5MG
VARINIL® TABLETS 10MG

PRESENTATION:
Varinil® Tablets 5mg: White, oblong, flat bevelled edge tablet embossed 'COSMOS' on one side and a breakline on the other side. Each tablet contains: Amlodipine Besylate equivalent to Amlodipine 5mg.
Varinil® Tablets 10mg: White, circular, biconvex, flat bevelled edge tablet embossed 'C' on one side and '10' on the other side. Each tablet contains: Amlodipine Besylate equivalent to Amlodipine 10mg.

CLINICAL PHARMACOLOGY:
Amlodipine is a dihydropyridine calcium - channel blocker. It is a peripheral and coronary vasodilator, but, unlike the calcium - channel blockers verapamil or diltiazem, has little or no effect on cardiac conduction and negative inotropic activity is rarely seen at therapeutic doses. Administration of Amlodipine results primarily in vasodilatation, with reduced peripheral resistance, blood pressure, and afterload, increased coronary blood flow, and a reflex increase in heart rate. This in turn results in an increase in myocardial oxygen supply and cardiac output.

Pharmacokinetics:
Amlodipine is well absorbed following oral administration with peak blood concentrations occurring after 6 to 12 hours. The bioavailability varies but is usually about 60 to 65%. Amlodipine is reported to be about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half-life of 35 to 50 hours and steady-state plasma concentrations are not achieved until after 7 to 8 days of administration. Amlodipine is extensively metabolised in the liver; metabolites are mostly excreted in urine together with less than 10% of a dose as unchanged drug.

USES:
It is used in the management of hypertension and angina pectoris.

DOSAGE AND ADMINISTRATION:
Hypertension and stable angina pectoris:
The usual dose is 5mg once daily. If necessary, this may be increased to 10mg once daily.

CONTRA-INDICATIONS AND WARNINGS:
Precautions:
Amlodipine should be used with caution in patients with hypotension, in patients whose cardiac reserve is poor, and in those with heart failure since deterioration of heart failure has been noted. Amlodipine should not be used in cardiogenic shock, in patients who have recently suffered a myocardial infarction, or in acute unstable angina. Amlodipine should not be used to treat an anginal attack in chronic stable angina. In patients with severe aortic stenosis Amlodipine may increase the risk of developing heart failure. Sudden withdrawal of Amlodipine might be associated with an exacerbation of angina. The dose may need to be reduced in patients with hepatic impairment. Amlodipine should be discontinued in patients who experience ischaemic pain following its administration.

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Adverse Effects:
The most common adverse effects of amlodipine are associated with its vasodilator action and often diminish on continued therapy. They include dizziness, flushing, headache, hypotension, peripheral oedema, tachycardia, and palpitations. Nausea and other gastro-intestinal disturbances, increased micturition frequency, lethargy, eye pain and mental depression have also occurred. A paradoxical increase in ischaemic chest pain may occur at the start of treatment and in a few patients excessive fall in blood pressure has led to cerebral or myocardial ischaemia or transient blindness. There have been reports of rashes (including erythema multiforme), fever, and abnormalities in liver function, including cholestasis, due to hypersensitivity reactions. Gingival hyperplasia, myalgia, tremor, and impotence have been reported. Overdosage may be associated with bradycardia and hypotension.

Interactions:
Amlodipine may enhance the antihypertensive effects of other antihypertensive drugs such as beta blockers although the combination is generally well tolerated. Enhanced antihypertensive effects may also be seen with concomitant use of drugs such as aldesleukin and antipsychotics that cause hypotension. Amlodipine may modify insulin and glucose responses and therefore diabetic patients may need to adjust their antidiabetic treatment when receiving amlodipine

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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COSMOS

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