Module-1 Administrative Information and Product Information

1. Name of the medicinal Product

Amlokris 5 mg. Tablets (Amlodipine Besilate Tablets 5 mg)

2. Qualitative and Quantitative Composition

Each uncoated tablet contains:
Amlodipine Besilate BP ----------5mg.
Excipients----------q.s.

Quantitative declaration

Excipients with known effect:
Maize Starch, Microcrystalline Cellulose, Dibasic Calcium Phosphate, Sodium Starch Glycolate, Povidobne-90, Methyl Paraben, Propyl Paraben, Magnesium Stearate, Purified Talc, Colloidal Silicon Dioxide (Aerosil), Cross Carmelose Sodium & Sodium Starch Glycolate,
For a full list of excipients, see section 6.1

3. Pharmaceutical Form

Oral Tablet

White tablet color, uncoated embossed with single break line on one side and plain on other side.

4. Clinical Particulars

4.1 Therapeutic Indications

Amlodipine Besilate Tablets is indicated for hypertension, chronic stable angina and vasospastic angina (Prinzmetal's or variant angina). Amlodipine Besilate Tablets may be used as monotherapy or in combination with other antihypertensive or antianginal drugs.

4.2 Posology and Method of Administration

Hypertension: Initial dose of 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 and this dose may be used when adding amlodipine to other anti- hypertensive therapy. Chronic stable or vasospastic angina: 5 - 10 mg with a lower dose (2.5 mg) in the elderly and in patients with hepatic insufficiency.

Children: The effective antihypertensive oral dose in paediatric patients (6-17 years) is 2.5 mg to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in paediatric patients.

4.3 Contraindications

Hypersensitivity to amlodipine or any component of the formulation.

4.4 Special Warnings and Special Precautions for Use

Increased angina and/or MI has occurred with initiation or dosage titration of calcium channel blockers. Use caution in severe aortic stenosis. Use caution in patients with severe hepatic impairment. Dosage titration should occur after 7 - 14 days on a given dose.

Pregnancy Implications: Embryotoxic effects have been demonstrated in small animals. No well-controlled studies have been conducted in pregnant women. Use in pregnancy only when clearly needed and when the benefits outweigh the potential hazard to the fetus,

Lactation : Excretion in breast milk unknown/not recommended.

4.5 Interaction with other medicinal products and other forms of interaction

In clinical trials, amlodipine has been safely administered with thiazide diuretics, beta-Blockers, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual nitroglycerin, digoxin warfarin, non steroidal anti-inflammatory drugs, antibiotics and oral hypoglycemic drugs.

4.6 Fertility, Pregnancy and Lactation

Pregnancy Implications: Embryotoxic effects have been demonstrated in small animals. No well-controlled studies have been conducted in pregnant women. Use in pregnancy only when clearly needed and when the benefits outweigh the potential hazard to the fetus,

Lactation : Excretion in breast milk unknown/not recommended.

4.7 Effects on ability To Drive and use Machines

None.

4.8 Undesirable Effects

Amlodipine is well tolerated. Side effects include headache, oedema, fatigue, somnolence, nausea, abdominal pain, flushing, palpitations and dizziness.

Less commonly observed are pruritus, rash, dyspnoea, asthenia, muscle cramps and dyspepsia. Rarely, myocardial infarction and chest pain have been reported.

4.9 Overdose

Primary cardiac symptoms of calcium channel blocker overdose include hypotension and bradycardia. Noncardiac symptoms include confusion, stupor, nausea, vomiting, metabolic acidosis, and hyperglycemia. Treat other s1gns and symptoms symptomatically.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Inhibits calcium ion from entering the "slow channels" or select voltage-sensitive areas of vascular smooth muscle and myocardium during depolarization, producing a relaxation of coronary vascular smooth muscle and coronary vasodilation; increases myocardial oxygen delivery in patients with vasospastic angina.

5.2 Pharmacokinetic Properties

After oral administration of therapeutic doses of amlodipine, absorption produces peak plasma concentrations between 6 and 12 hours. Absolute bioavailability has been estimated to be between 64 and 90°/o. The bioavailability of amlodipine is not altered by the presence of food 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. Elimination from the plasma is biphasic with a terminal elimination half-life of about 30-50 hours. SteadyState plasma levels of amlodipine are reached after 7 to 8 days of consecutive daily dosing.

The pharmacokinetics of amlodipine are not significantly influenced by renal impairment. Patients with renal failure may therefore receive the usual initial dose.

Elderly: patients and patients with hepatic insufficiency have decreased clearance of amlodipine with a resulting: increase m AUC of approximately 40-60%, and a lower initial dose may be required. A similar increase in A UC was observed in patients with moderate to severe heart failure.

Paediatric Patients: Sixty-two hypertensive patients aged 6 to 17 years received doses of amlodipine between 1.25 mg and 20 mg. Weight-adjusted clearance and volume of distribution were similar to values in adults.

5.3 Preclinical Safety Data

No other relevant preclinical data is available.

6. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch, Microcrystalline Cellulose, Dibasic Calcium Phosphate, Sodium Starch Glycolate, Povidobne-90, Methyl Paraben, Propyl Paraben, Magnesium Stearate,
Purified Talc, Colloidal Silicon Dioxide (Aerosil), Cross Carmelose Sodium & Sodium Starch Glycolate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C. Protect from light & moisture.

6.5 Nature and Contents of Container

The tablets are packed in Alu/PVC blister and inserted in a mono carton. Pack sizes: 2x14 Tablet.

6.6 **Special precaution for disposal and other handling**

Any unused product or waste material should be disposed of in accordance with local requirements. Keep the medicine out of reach of children

7. Manufacturing By

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