SUMMARY OF PRODUCTCHARACTERISTICS

1. Name of the Medicinal Product

1.1 Product Name: Klodip-5 (Amlodipine Besilate Tablets 5mg)

1.2 Strength: 5 mg

1.3 Pharmaceutical Form: Tablets

2. Qualitative and Quantitative Composition

Qualitative declaration:

Each uncoated tablet contains:

Amlodipine Besilate BP equivalent to Amlodipine…. 5mg

Quantitative declaration:

Sr. No.	Ingredient	Purpose of inactive	Quantity Per Tablets (mg)
1	Amlodipine Besilate BP	Active	7.00

3. Pharmaceutical form

Amlodipine Besilate Tablets 5mg are white, circular, flat, beveled tablets with break line on one side plain on other side without any visible defects.

4 Clinical Particulars

4.1 Therapeutic indications

Amlodipine Besilate Tablets is indicated in the treatment of hypertension either alone or in ombination with other antihypertensive agents. It is also indicated in the treatment of chronic stable angina and vasospastic angina.

4.2 Posology and Method of Administration

The usual antihypertensive oral dose of Amlodipine Besilate Tablets is 5mg Once daily with a maximum dose of 10mg once daily. Small fragile or elderly individuals or patients with hepatic insufficiency may be started with 2.5mg once daily dose.Dosage should be adjusted according to each patients need and titration should proceed over 7-14 days for a physician to assess patients response to each dose level.

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

No dose adjustment is required during combined administration of thiazide diuretics, betablockers, or angiotensin converting enzyme inhibitors, long acting nitrates, sub lingual nitroglycerine.

Amlodipine Besilate Tablets are not recommended for use in children.

Route of administration: Oral

4.3 Contraindications

Amlodipine is contraindicated in patients hypertensive to amlodipine.

4.4 Special warnings and precautions for use

Rarely, patients particularly those with obstructive coronary artery disease, have developed documentary 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.

For the risk of hypotention, caution should be exercised while administering Amlodipine

Besilate Tablets with any other vasodilator, particularly in patients with severe aortic stenosis. Caution should be taken while administering Amlodipine Besilate Tablets 10mg in patients with severe hepatic impairment.

4.5 Interactions with other medicinal products and other forms of interactions

Amlodipine Besilate Tablets may be administered with thiazide diuretics, beta blockers, angiotensin converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerine, nonsteroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic medicines.

4.6 Pregnancy and Lactation

Safety of Amlodipine Besilate tablets in human pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machine

Amlodipine can have minor or moderate influence on the ability to drive and use machines. If patients taking amlodipine suffer from dizziness, headache, fatigue or nausea the ability to react may be impaired. Caution is recommended especially at the start of treatment.

4.8 Undesirable effects

In general, treatement with Amlodipine is well tolerated at doses upto 10mg daily. Most adverse reactions during the therapy are of mild to moderate severity. The most common dose related adverse effectsare edema, dizziness, flushing, palpitation. Other side effects which are not clearly dose related are headache, fatigue, nausea abdominal pain and somnolence.

4.9 Overdose

Gross over dosage could result in excessive peripheral vasodilation with subsequently marked and probably prolonged systematic hypotension. Provide active cardiovascular support. Intravenous calcium gluconate may be benficial in reversing the effects of calcium channel blockade. If hypotension remains unresponsive, administration of vasopressors (such as phenylephrine) should be considered with attention to circulating volume and urine output. Amlodipine is highly protein bound, dialysis is not likely to be of benefit.

5.0 Pharmacological properties

5.1 Pharmacological Properties

Amlodipine Besilate is a dihydropyridine calcium antagonist that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Amlodipine binds to both dihyropyridine and nondihydropyridine binding sites. The contractile processes of cardiac muscles and vascular smooth muscles are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membrane selectivity, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscles to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

5.2 Pharmacokinetic properties

Absorption, distribution, plasma protein binding:

After oral administration of therapeutic doses, amlodipine is well absorbed with peak blood levels between 6-12 hours post dose. Absolute bioavailability has been estimated to be between 64 and 80%. The volume of distribution is approximately 21 l/kg. In vitro studies have shown that approximately 97.5% of circulating amlodipine is bound to plasma proteins.

The bioavailability of amlodipine is not affected by food intake.

Biotransformation/elimination

The terminal plasma elimination half life is about 35-50 hours and is consistent with once daily dosing. Amlodipine is extensively metabolised by the liver to inactive metabolites with 10% of the parent compound and 60% of metabolites excreted in the urine.

Use in the elderly: The time to reach peak plasma concentrations of amlodipine is similar in elderly and younger subjects. Amlodipine clearance tends to be decreased with resulting increases in AUC and elimination half-life in elderly patients. Increases in AUC and elimination half-life in patients with congestive heart failure were as expected for the patient age group studied.

5.3 Preclinical safety data

Amlodipine Besilate is not teratogenic or genotoxic. Long-term carcinogenic potential of Amlodipine Besilate has not been investigated. The pharmacodynamics, pharmacokinetics and toxicological properties of Amlodipine Besilate are well known. No preclinical data has been supplied with this application and none are required for applications of this type.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Maize starch, Microcrystalline Cellulose, Calcium Hydrogen Phosphate, Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica, Microcrystalline Cellulose, Crospovidone.

6.2 Incompatibilities

None

6.3 Shelf life

36 Months (3Years)

6.4 Special precautions for storage

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

6.5 Nature and contents of container

ALU/ PVC Blister Pack of 10 X 3 X 10's tablets.

6.6 Special Precaution for disposal

None

7. Manufacturer

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8. Number(s) in the National Register of Finished Pharmaceutical Products

09137/08594/REN/2022

9. Date of first authorisation/renewal of the authorisation

Dec 4, 2023

10. Date of revision of text

Not applicable