SHALDIP 10
Amlodipine Besylate Tablets USP 10 mg

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

1.1 Product Name: SHALDIP 10 (Amlodipine Besylate Tablets USP 10 mg)

1.2 Strength

Composition:

Each film coated tablet contains:

Amlodipine Besylate USP equivalent to Amlodipine…….10 mg

Colours: Titanium Dioxide & Brilliant Blue

1.3 Pharmaceutical/Dosage form: Oral Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Raw Materials	Specification	Quantity per Tablet (mg)	Category
1	Amlodipine Besylate	USP	13.880	Active Ingredient
2	Dibasic Calcium Phosphate Anhydrous	BP	41.000	Diluent
3	Maize Starch	BP	45.210	Diluent
4	Maize Starch (Paste)	BP	10.000	Binder
5	Colour Brilliant Blue FCF	IH	0.006	Coloring agent
6	Purified Talc	BP	2.000	Glident
7	Magnesium Stearate	BP	2.000	Lubricant
8	Instacoat Aqua – III–40390 (Blue)	IH	3.000	Coloring agent

1mg of Amlodipine is equivalent to 1.388 mg of Amlodipine Besylate USP.

Definitions:

BP: British Pharmacopoeia

USP: United State Pharmacopoeia

IH: In-House Specifications

3. PHARMACEUTICAL FORM

Tablet (Oral)- Blue coloured circular biconvex film coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Shaldip 10 Tablets are indicated in the treatment of following:

1. Hypertension

2. Chronic Stable Angina

3. Vasospastic Angina (Prinzmetal's or Variant Angina)

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4.2 Posology and method of administration

Posology/Dosage:

Dosage should be adjusted according to each patient's need. In general, titration should proceed over 7 to 14 days so that the physician can fully assess the patient' response to each dose level. Titration may proceed more rapidly, however, if clinically warranted, provided the patient is assessed frequently.

Hypertension: 5 mg once daily. Max. 10 mg once daily. In case of 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 Tablets to other antihypertensive therapy. Chronic stable or vasospastic angina: 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.

Co-administration with other Antihypertensive and/or Antianginal Drugs: Amlodipine Tablets has been safely administered with thiazides, ACE inhibitors, beta-blocker, long-acting nitrates, and/or sublingual nitroglycerin.

Method of Administration: Tablets (Oral)

4.3 Contraindications

Shaldip 10 is contra-indicated in patients with known hypersensitivity to amlodipine

4.4 Special warnings and precautions for use

Rarely there can be increased angina or AMI in patients of severe CAD on starting or increasing of Shaldip. As with any other vasodilator in severe aortic stenosis it can cause acute hypotension.

Pediatric - Effect of Amlodipine in patients of less than 6 yrs of age is not known.

Geriatric - Experience in 65 years & older persons is not known, dose selection should be cautious starting with a low dose.

Hepatic failure - Since amlodipine is extensively metabolized by liver, caution should be exercised when administering to patients of hepatic failure.

4.5 Interaction with other drug products and other forms of interaction

ACE inhibitors, Thiazide diuretics: Potentiates effect of these drugs.

Beta Blockers: Beta Blockers avoided, especially by those with impaired LV function due to depressant effect on myocardial contractibility or AV conduction.

Fentanyl: Severe hypotension or increased fluid volume requirements.

4.6 Fertility, pregnancy and lactation

Usage in Pregnancy & Lactation: Shaldip 10 should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in nursing mothers - It is not known whether amlodipine is excreted in human milk.

In the absence of this information, it is recommended to use the drug only if it clearly needed by nursing mothers.

4.7 Effects on ability to drive and use machines

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

Some of the rarely observed adverse reactions are arrhythmia (including ventricular tachycardia and atrial fibrillation), bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, postural dizziness, postural hypotension, vasculitis, neuropathy peripheral, paresthesia, tremor, vertigo, sexual dysfunction (male** and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization.

Some of the commonly observed side effects with use of Shaldip 10 Tablets are headache, flushing, hypotension, nausea, abdominal pain, peripheral odema, fatigue, dizziness, palpitation, somnolence, rash etc.

4.9 Symptoms of Overdosage & Treatment

In humans experience with intentional overdose is limited. If accidental overdoasge happens, active cardiac & respiratory monitoring, frequent BP monitoring is required. If hypotension occurs then extremities should be raised & judicious administration of fluids is recommended. If hypotension is unresponsive to these measures, then vasopressors should be considered with attention to circulatory volume & urine output. IV calcium gluconate may help to reverse the calcium channel blockade.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Calcium channel blockers

ATC code: C08CA01

Pharmacological Category: Antihypertensive

5.1 Pharmacodynamic properties

Mechanism of action: Shaldip 10 is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. Shaldip 10 Tablets binds to both dihydropyridine and nondihydropyridine

binding sites. Shaldip 10 Tablets inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Serum calcium concentration is not affected by Amlodipine Besylate Tablets.

Shaldip 10 Tablets is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure. Shaldip 10 Tablets is also to reduce the total peripheral resistance (afterload) against which the heart works and reduces the rate pressure product, and thus myocardial oxygen demand, at any given level of exercise. Shaldip 10 Tablets has been demonstrated to block constriction and restore blood flow in coronary arteries and arterioles in response to calcium, potassium epinephrine, serotonin, and thromboxane A2 analog in experimental animal models and in human coronary vessels.

5.2 Pharmacokinetic properties

• Oral Absorption- 60-80 %

• Presystemic Metabolism - < 5 %

• Plasma half-life

Range - 30 - 60 h

Mean - 36 h

• Volume of distribution - 21 l.kg-1

• Plasma protein binding 92 - 95 %

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic Calcium Phosphate Anhydrous BP, Maize Starch BP, Purified Talc BP, Magnesium Stearate BP, Hypromellose BP, Macragols BP, Lactose BP

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

Shaldip 10 is available in blister pack of 10 Tablets. 3 such filled blisters are packed in a printed carton along with one leaflet.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

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