# SUMMARY OF PRODUCT CHARACTERISTICS
## DIPMAR-5 (Amlodipine Besylate Tablets USP 5 mg)

## 1. NAME OF THE MEDICINAL PRODUCT

DIPMAR-5 (Amlodipine Besylate Tablets USP 5 mg)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains amlodipine besylate USP equivalent to amlodipine 5 mg.

**Excipients with known effect:**

Contains lactose (as dibasic calcium phosphate contains no lactose — see section 4.4 regarding lactose-related hereditary conditions). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablet (uncoated).

White, circular, flat, bevelled-edge, uncoated tablet with a break-line on one side and plain on the other side.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

DIPMAR-5 is indicated for:

- Essential hypertension.
- Chronic stable angina pectoris.
- Vasospastic (Prinzmetal's) angina.

### 4.2 Posology and method of administration

**Adults**

For both hypertension and angina, the usual initial dose is 5 mg amlodipine once daily, which may be increased to a maximum dose of 10 mg once daily depending on the individual patient's response.

For angina, amlodipine may be used as monotherapy or in combination with other antianginal medicinal products in patients with angina refractory to nitrates and/or adequate doses of beta-blockers.

In hypertensive patients, amlodipine has been used in combination with a thiazide diuretic, alpha-blocker, beta-blocker or ACE inhibitor. No dose adjustment of amlodipine is required upon concomitant administration of these agents.

**Elderly patients**

Amlodipine should be initiated at the lower end of the dosing range. Slow dose titration and careful monitoring may be required in patients with severe hepatic impairment.

**Hepatic impairment**

Amlodipine's half-life is prolonged and AUC values are higher in patients with impaired liver function. Dosage recommendations have not been established; the drug should be administered with caution, beginning at the lower end of the dosing range.

**Renal impairment**

Changes in amlodipine plasma concentrations are not correlated with the degree of renal impairment. Normal doses can therefore be used.

**Paediatric population**

Children and adolescents with hypertension aged 6–17 years: Recommended dose is 2.5–5 mg once daily. Children below 6 years: no data available.

**Method of administration**

Oral. May be taken with or without food.

### 4.3 Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
- Shock (including cardiogenic shock).
- Obstruction of the outflow tract of the left ventricle (e.g. high-grade aortic stenosis).
- Unstable angina (excluding Prinzmetal's angina).
- Severe hypotension.
- Haemodynamically unstable heart failure after acute myocardial infarction.

## 4.4 Special warnings and precautions for use

**Heart failure**

Patients with heart failure should be treated with caution. In a long-term placebo-controlled study in patients with severe heart failure (NYHA class III and IV), the reported incidence of pulmonary oedema was higher in the amlodipine group than in the placebo group. Calcium channel blockers, including amlodipine, should be used with caution in patients with congestive heart failure, as they may increase the risk of future cardiovascular events and mortality.

**Hepatic impairment**

Amlodipine's half-life is prolonged and AUC values are higher in patients with impaired liver function; the drug should be administered with caution. Slow dose titration and careful monitoring may be required in severe hepatic impairment.

**Patients with hereditary problems of galactose intolerance**

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

## 4.5 Interaction with other medicinal products and other forms of interaction

**CYP3A4 inhibitors:**

Concomitant use with strong or moderate CYP3A4 inhibitors (protease inhibitors, azole antifungals, macrolides such as erythromycin or clarithromycin, verapamil or diltiazem) may significantly increase amlodipine exposure resulting in an increased risk of hypotension. Clinical monitoring and dose adjustment may be required, particularly in the elderly.

**CYP3A4 inducers:**

Upon co-administration of known CYP3A4 inducers, amlodipine plasma concentration may be reduced; blood pressure should be monitored and dose regulation considered, particularly with strong CYP3A4 inducers (e.g. rifampicin, Hypericum perforatum).

**Grapefruit/grapefruit juice:**

Not recommended; bioavailability may be increased in some patients, resulting in increased blood pressure-lowering effects.

**Dantrolene (infusion):**

Due to risk of hyperkalaemia, co-administration of calcium channel blockers including amlodipine should be avoided in patients susceptible to malignant hyperthermia.

**Simvastatin:**

Co-administration of multiple doses of amlodipine 10 mg with simvastatin 80 mg resulted in a 77% increase in simvastatin exposure. Limit the dose of simvastatin in patients on amlodipine to 20 mg daily.

**Tacrolimus:**

Risk of increased tacrolimus blood levels; monitor tacrolimus blood levels and adjust dose as appropriate.

**Ciclosporin:**

In renal transplant patients, variable trough concentration increases (average 0–40%) have been observed; consider monitoring ciclosporin levels.

Blood pressure-lowering effects of amlodipine add to those of other antihypertensive agents. No clinically significant interactions with atorvastatin, digoxin, warfarin, cimetidine or sildenafil have been identified.

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Use in pregnancy is only recommended when there is no safer alternative and when the disease itself carries greater risk for the mother and foetus.

**Breast-feeding**

Amlodipine is excreted in human milk. The proportion received by the infant has been estimated with an interquartile range of 3–7%, with a maximum of 15%. The effect of amlodipine on infants is unknown. A decision should be made whether to continue/discontinue breast-feeding or to continue/discontinue amlodipine therapy, taking into account the benefit of breast-feeding to the child and the benefit of therapy to the mother.

**Fertility**

Some calcium channel blockers have been associated with reversible biochemical changes in the head of spermatozoa. Insufficient data are available regarding potential effects of amlodipine on fertility in humans.

### 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 suffer from dizziness, headache, fatigue or nausea, the ability to react may be impaired, particularly at the start of treatment.

### 4.8 Undesirable effects

**Summary of the safety profile**

The most commonly reported adverse reactions during treatment are somnolence, dizziness, headache, palpitations, flushing, abdominal pain, nausea, ankle swelling, oedema and fatigue. Adverse events are generally mild to moderate.

| System Organ Class | Very common / Common | Uncommon | Rare / Very rare |
|---|---|---|---|
| Nervous system | Headache, somnolence, dizziness | Tremor, dysgeusia, syncope, hypoaesthesia, paraesthesia | Peripheral neuropathy, extrapyramidal disorder |
| Eye | | Visual impairment, diplopia | |
| Cardiac | Palpitations | Arrhythmias (bradycardia, ventricular tachycardia, AF) | Myocardial infarction |
| Vascular | Flushing | Hypotension | Vasculitis |
| Respiratory | | Dyspnoea, rhinitis | Cough |
| Gastrointestinal | Nausea, abdominal pain | Vomiting, dyspepsia, altered bowel habits, dry mouth | Gingival hyperplasia, pancreatitis |
| Skin and subcutaneous | | Alopecia, rash, pruritus, urticaria, exanthema, hyperhidrosis, purpura | Angioedema, erythema multiforme, SJS |
| Musculoskeletal | | Arthralgia, myalgia, muscle cramps, back pain | |
| Renal and urinary | | Pollakiuria, micturition disorder, nocturia | |
| Reproductive | | Impotence, gynaecomastia | |
| General | Oedema, fatigue | Chest pain, pain, asthenia, malaise | Weight increase/decrease |
| Investigations | | Elevated liver enzymes | Elevated serum creatinine |
| Immune system | | Hypersensitivity | Very rare: allergic reactions |

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

### 4.9 Overdose

Gross overdosage could result in excessive peripheral vasodilatation and possibly reflex tachycardia. Marked and potentially prolonged systemic hypotension, including fatal shock, has been reported.

Treatment: Activated charcoal to healthy volunteers immediately or up to 2 hours after ingestion has been shown to significantly reduce amlodipine absorption. Gastric lavage may be worthwhile. Clinically significant hypotension requires active cardiovascular support including frequent monitoring of cardiac and respiratory function, elevation of extremities, and attention to circulating fluid volume and urine output. A vasoconstrictor may be helpful in restoring vascular tone. Intravenous calcium gluconate may be beneficial to reverse the effects of calcium channel blockade. Since amlodipine is highly protein-bound, dialysis is not likely to be of benefit.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Calcium channel blockers — dihydropyridine derivatives. ATC code: C08CA01.

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. The antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle. In patients with hypertension, once-daily dosing provides clinically significant reductions of blood pressure in both supine and standing positions throughout the 24-hour interval. Due to the slow onset of action, acute hypotension is not a feature of amlodipine administration.

For angina, amlodipine reduces total ischaemic burden by: (1) dilating peripheral arterioles and reducing total peripheral resistance (afterload), thereby reducing myocardial energy consumption and oxygen requirements; (2) dilating main coronary arteries and coronary arterioles, increasing myocardial oxygen delivery — particularly in vasospastic (Prinzmetal's) angina.

### 5.2 Pharmacokinetic properties

Absorption: Well absorbed after oral administration; peak blood levels 6–12 hours post-dose. Absolute bioavailability estimated at 64–80%. Food intake does not affect bioavailability. Distribution: Volume of distribution approximately 21 L/kg; approximately 97.5% bound to plasma proteins in vitro. Biotransformation/elimination: Extensively metabolised by the liver to inactive metabolites. Terminal plasma elimination half-life approximately 35–50 hours (consistent with once-daily dosing). 10% of the parent compound and 60% of metabolites excreted in urine.

### 5.3 Preclinical safety data

Not available from the submitted SmPC. Amlodipine has an extensive clinical safety record; no additional preclinical concerns have been identified beyond those known for the class.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| No. | Excipient | Specification |
|---|---|---|
| 1 | Dibasic calcium phosphate | BP |
| 2 | Sodium starch glycolate | BP |
| 3 | Maize starch | BP |
| 4 | Titanium dioxide (E171) | BP |
| 5 | Povidone K-30 | BP |
| 6 | Purified water | BP |
| 7 | Magnesium stearate | BP |
| 8 | Purified talc | BP |

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

### 6.5 Nature and contents of container

10 tablets per blister; 3 such blisters packed in a printed carton with package insert. Pack size: 30 tablets.

### 6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

**ZAIN PHARMA LTD.**

Plot No. 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

## 8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12568/25449

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

21.01.2026

## 10. DATE OF REVISION OF THE TEXT

21.01.2026