SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

Stamvex 10 mg Tablets

(Each tablet contains Amlodipine besilate equivalent to 10 mg of Amlodipine)

2. Qualitative and Quantitative Composition

Each film-coated tablet contains:

- Amlodipine besilate equivalent to 10 mg Amlodipine.

Excipients:

Microcrystalline cellulose, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide, lactose monohydrate, povidone, and film-coating agents (hypromellose, titanium dioxide, polyethylene glycol).

3. Pharmaceutical Form

Film-coated tablet.

White to off-white, round, biconvex tablets debossed with “SVX10” on one side and plain on the other.

4. Clinical Particulars

4.1 Therapeutic Indications

Stamvex (Amlodipine 10 mg) is indicated for:

- Hypertension: as monotherapy or in combination with other antihypertensives.
- Chronic stable angina pectoris.
- Vasospastic (Prinzmetal’s) angina.
- Coronary artery disease (CAD): proven reduction in risk of hospitalization for angina and revascularization procedures.

4.2 Posology and Method of Administration

Adults:

- Initial dose: 5 mg once daily.
- Maximum dose: 10 mg once daily.
- In resistant cases or severe hypertension, 10 mg once daily is recommended.

Elderly:

- Normal dosage, but caution due to possible decreased clearance.

Renal impairment:

- No dose adjustment required.

Hepatic impairment:

- Dose reduction may be required; start at 2.5–5 mg.

Paediatric population (6–17 years):

- Recommended starting dose is 2.5 mg once daily (non-scored tablets may limit use).
- Maximum: 5 mg/day.

Administration:

- Oral use. May be taken with or without food. Administer at the same time each day.

4.3 Contraindications

- Known hypersensitivity to amlodipine, dihydropyridine derivatives, or excipients.
- Severe hypotension (systolic BP <90 mmHg).
- Shock (including cardiogenic shock).
- Obstruction of outflow tract of the left ventricle (e.g., high grade aortic stenosis).
- Unstable angina (excluding vasospastic angina).
- Heart failure after acute myocardial infarction (within 28 days).

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with:
- Heart failure (may increase risk of pulmonary oedema).
- Hepatic impairment (requires lower starting dose).
- Severe hypotension or hypovolaemia.
- May cause peripheral oedema; dose adjustment or combination with ACE inhibitors/diuretics may be required.
- Avoid abrupt withdrawal.

4.5 Interaction with Other Medicinal Products

- CYP3A4 inhibitors (ketoconazole, itraconazole, ritonavir, diltiazem, clarithromycin) may increase plasma concentration of amlodipine.
- CYP3A4 inducers (rifampicin, St. John's Wort, carbamazepine, phenytoin) may reduce plasma concentration.
- Grapefruit juice has no significant effect.
- Potentiates antihypertensive effect when combined with other agents (ACE inhibitors, diuretics, beta-blockers).
- No significant interactions with digoxin, warfarin, or atorvastatin.

4.6 Fertility, Pregnancy and Lactation

- Pregnancy: Limited data; use only if benefits outweigh risks.
- Lactation: Amlodipine is excreted in breast milk; not recommended during breastfeeding.
- Fertility: Reversible biochemical changes in sperm head have been observed in animal studies; clinical relevance unclear.

4.7 Effects on Ability to Drive and Use Machines

May cause dizziness, headache, fatigue, or nausea. Caution is advised when driving or operating machinery until individual response is known.

4.8 Undesirable Effects

- Very common (>1/10): Peripheral oedema.
- Common (≥1/100 to <1/10): Headache, dizziness, drowsiness, palpitations, flushing, abdominal pain, nausea, fatigue.
- Uncommon (≥1/1000 to <1/100): Vomiting, dyspepsia, visual disturbances, hypotension, rash, pruritus, dyspnoea, muscle cramps.
- Rare (≥1/10,000 to <1/1000): Hepatitis, jaundice, gynecomastia, angioedema.
- Very rare (<1/10,000): Stevens-Johnson syndrome, toxic epidermal necrolysis, myocardial infarction, arrhythmias.

Report adverse reactions via the national pharmacovigilance system.

4.9 Overdose

- Symptoms: Severe hypotension, reflex tachycardia, prolonged systemic vasodilation, shock (potentially fatal).
- Management: Supportive treatment, active cardiovascular support, monitoring of cardiac/respiratory function, elevation of extremities, intravenous fluids. Vasoconstrictors (norepinephrine) may be useful. IV calcium gluconate may reverse calcium channel blockade. Amlodipine is not dialyzable.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Calcium channel blockers, dihydropyridine derivatives

ATC code: C08CA01

- Inhibits calcium ion influx across vascular smooth muscle and myocardium.
- Reduces peripheral vascular resistance → lowers blood pressure.
- Increases coronary blood flow in angina patients.
- Long half-life ensures once-daily dosing.

5.2 Pharmacokinetic Properties

- Absorption: Bioavailability 64–80%. Peak plasma concentration in 6–12 hrs.
- Distribution: Extensive; 97.5% bound to plasma proteins.
- Metabolism: Extensively metabolized in the liver to inactive metabolites.
- Elimination half-life: 30–50 hrs.
- Excretion: Urine (60% as metabolites, 10% unchanged).

5.3 Preclinical Safety Data

- No evidence of carcinogenicity in rats or mice.
- Reproductive studies in animals: delayed parturition and prolonged labour.
- No mutagenic effects observed.

6. Pharmaceutical Particulars

6.1 List of Excipients

- Microcrystalline cellulose
- Sodium starch glycolate
- Povidone
- Magnesium stearate
- Lactose monohydrate
- Colloidal silicon dioxide
- Film-coating materials: hypromellose, titanium dioxide, polyethylene glycol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months.

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

PVC/Aluminum foil blisters in packs of 10, 20, 30, or 100 tablets.

6.6 Special Precautions for Disposal

Dispose according to local regulations. No special requirements.

7. Marketing Authorization Holder/Manufacturer

A.C. Drugs Limited

Plot C5/C6 Old Airport Road

Emene, Enugu, Nigeria

8. Marketing Authorization Number

9. Date of First Authorization/Renewal

10. Date of Revision of the Text

September 2025

11.Legal Category

Prescription only Medicine (Rx)