VEGALOD TABLETS

(Amlodipine Besylate 5 mg & 10 mg)

COMPOSITION

Each Vegalod 5 mg tablet contains Amlodipine Besylate equivalent to Amlodipine 5 mg. Each Vegalod 10 mg tablet contains Amlodipine Besylate equivalent to Amlodipine 10 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Amlodipine is a long-acting dihydropyridine calcium-channel blocker. It inhibits calcium influx into vascular smooth muscle and cardiac muscle, causing peripheral arterial vasodilation and lowering blood pressure. It also reduces myocardial ischaemia through coronary and peripheral vasodilation.

INDICATIONS

Hypertension, alone or with other antihypertensive medicines; chronic stable angina; vasospastic (Prinzmetal) angina; and selected patients with angiographically documented coronary artery disease, subject to locally approved indications.

DOSAGE & ADMINISTRATION

For oral use once daily, with or without food. Adults: usual initial dose 5 mg once daily; maximum 10 mg once daily. Adjust according to blood-pressure response and tolerability, usually after 7 to 14 days.

ADDITIONAL DOSAGE GUIDANCE

Small, frail or elderly patients, and patients with hepatic insufficiency, may require an initial dose of 2.5 mg daily using an appropriate dosage form. Vegalod is supplied as 5 mg and 10 mg tablets; do not assume tablets can be divided unless the approved product specifications permit it.

For angina or coronary artery disease, usual adult dose is 5 to 10 mg once daily. Do not exceed the prescribed daily dose.

PAEDIATRIC USE

For hypertension in children aged 6 to 17 years, doses of 2.5 to 5 mg once daily have been studied. Doses above 5 mg daily have not been studied in this population. An appropriate formulation is needed for 2.5 mg doses. Safety and effectiveness under 6 years have not been established.

ELDERLY & ORGAN IMPAIRMENT

Start cautiously in older or frail patients. Titrate slowly in hepatic impairment because amlodipine exposure may increase. Renal impairment generally does not require dose adjustment, but clinical monitoring remains important.

CONTRAINDICATIONS

Known hypersensitivity to amlodipine or any ingredient of the formulation.

WARNINGS & PRECAUTIONS

Symptomatic hypotension may occur, especially in patients with severe aortic stenosis. Worsening angina or acute myocardial infarction can occur after initiating therapy or increasing the dose, particularly in severe obstructive coronary artery disease.

Monitor blood pressure, dizziness, peripheral oedema and treatment response. Amlodipine does not provide immediate relief of an acute angina attack. Avoid abrupt self-directed treatment changes.

DRUG INTERACTIONS

Strong or moderate CYP3A inhibitors may increase amlodipine exposure; monitor for hypotension and oedema. CYP3A inducers may alter exposure. When used with simvastatin, limit simvastatin to 20 mg daily. Amlodipine may increase exposure to tacrolimus or ciclosporin; monitoring may be needed. Other blood-pressure-lowering medicines may increase hypotensive effects.

PREGNANCY & LACTATION

Use in pregnancy only after individual assessment of maternal benefit and fetal risk; uncontrolled hypertension also carries risks. Amlodipine is present in human milk; consider benefits of breastfeeding, maternal treatment needs and potential infant effects.

DRIVING & MACHINERY

Dizziness or fatigue may impair performance, particularly after starting treatment or increasing the dose.

ADVERSE REACTIONS

Peripheral oedema is common and dose related. Other reported reactions include dizziness, flushing, palpitations, fatigue, headache, nausea, abdominal pain and somnolence. Rare serious reactions include marked hypotension, hypersensitivity and worsening angina. Seek medical care for severe symptoms.

OVERDOSAGE

Overdose can cause excessive peripheral vasodilation, prolonged hypotension, reflex tachycardia and potentially shock. Seek emergency medical attention. Supportive cardiovascular monitoring and treatment are required; dialysis is unlikely to be effective.

STORAGE CONDITIONS

Store according to the approved product storage specifications, protected from excess heat and moisture. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Vegalod Tablets 5 mg: pack of 20 tablets.
Vegalod Tablets 10 mg: pack of 20 tablets.

PATIENT ADVICE

Take once daily as prescribed, preferably at the same time each day. Do not change the dose without medical advice. Monitor blood pressure and report troublesome ankle swelling, severe dizziness, fainting or chest pain.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.