VEGAPROL TABLETS

Bisoprolol Fumarate 2.5 mg, 5 mg and 10 mg
Oral tablets | Pack sizes: 14 and 2 x 10

COMPOSITION

Each tablet contains Bisoprolol Fumarate 2.5 mg, 5 mg or 10 mg, as indicated on the pack. Excipients are according to the approved Vegaprol formulation.

THERAPEUTIC CLASS

Selective beta-1 adrenergic receptor blocker (cardioselective beta-blocker); antihypertensive and antianginal medicine.

PHARMACOLOGY

Bisoprolol selectively blocks cardiac beta-1 adrenergic receptors, reducing heart rate, myocardial contractility and renin release. It lowers blood pressure and myocardial oxygen demand. Cardioselectivity is dose-dependent and does not eliminate bronchospasm risk.

INDICATIONS

Management of hypertension. In jurisdictions where approved: chronic stable angina pectoris and stable chronic heart failure with reduced left ventricular systolic function, as part of appropriate combination therapy. Use only for indications approved for Vegaprol.

DOSAGE: HYPERTENSION / ANGINA

Adults: Common initial dose 5 mg orally once daily; 2.5 mg once daily may be appropriate in selected patients. Adjust according to response, commonly to 10 mg once daily. Some hypertension/angina references allow up to 20 mg/day; use the approved indication-specific maximum. Assess blood pressure and pulse during titration.

DOSAGE: STABLE CHRONIC HEART FAILURE

Only where locally approved and under specialist supervision: Start 1.25 mg once daily for 1 week, then 2.5 mg for 1 week, 3.75 mg for 1 week, 5 mg for 4 weeks, 7.5 mg for 4 weeks and 10 mg once daily thereafter, if tolerated. **Maximum: 10 mg/day for heart failure.** Lower strengths or appropriately scored tablets are needed for certain steps. Do not start during acute decompensation.

ADMINISTRATION

Take once daily, preferably in the morning, with or without food. Swallow with water. Do not chew. Do not split tablets unless the specific Vegaprol tablet is approved as divisible. Take a missed dose when remembered unless close to the next dose; do not double doses.

RENAL / HEPATIC IMPAIRMENT

For hypertension, with creatinine clearance below 40 mL/min or significant hepatic disease, an initial dose of 2.5 mg daily with cautious titration is recommended in US labeling. Other regional labels recommend a maximum of 10 mg daily in severe renal or hepatic impairment. Follow local approved instructions. Heart-failure titration requires particular caution.

CONTRAINDICATIONS

Hypersensitivity to bisoprolol or excipients; cardiogenic shock; acute heart failure or episodes of decompensated heart failure requiring intravenous inotropic therapy; marked bradycardia; second- or third-degree AV block without pacemaker; sick sinus syndrome or sinoatrial block; symptomatic hypotension. Additional restrictions may include severe asthma, severe peripheral arterial occlusive disease, metabolic acidosis and untreated phaeochromocytoma, according to approved labeling.

WARNINGS: ABRUPT WITHDRAWAL

Do not stop bisoprolol suddenly. Abrupt cessation may worsen angina or precipitate myocardial infarction, arrhythmias or heart failure, especially in coronary artery disease. When discontinuation is necessary, taper under medical supervision and monitor carefully.

WARNINGS AND PRECAUTIONS

Monitor for bradycardia, hypotension, heart block and worsening heart failure. Use caution in bronchospastic disease, diabetes (may mask tachycardia due to hypoglycaemia), hyperthyroidism, peripheral vascular disease and patients receiving general anaesthesia. In phaeochromocytoma, give an alpha-blocker before beta-blockade.

DRUG INTERACTIONS

Verapamil, diltiazem, digoxin and certain antiarrhythmics may increase bradycardia or AV block. Other antihypertensives may increase hypotension. Clonidine withdrawal requires careful sequencing. Insulin and oral antidiabetics: warning signs of hypoglycaemia may be masked. NSAIDs may reduce antihypertensive response. Review all concurrent medicines.

PREGNANCY AND BREASTFEEDING

Use during pregnancy only when the expected benefit justifies potential fetal risk; beta-blockers may affect fetal growth or cause neonatal bradycardia and hypoglycaemia. Breastfeeding data are limited; assess risks and monitor the infant if exposure occurs.

ADVERSE REACTIONS

Common effects include fatigue, dizziness, headache, cold extremities, nausea, diarrhoea or constipation. Serious effects include marked bradycardia, hypotension, AV block, worsening heart failure and bronchospasm. Seek urgent care for fainting, severe breathlessness or very slow heartbeat.

OVERDOSAGE

Overdose may cause severe bradycardia, hypotension, heart block, acute heart failure, bronchospasm and hypoglycaemia. Seek emergency care immediately. Management requires monitoring and supportive treatment under medical supervision.

STORAGE

Store in the original packaging according to the approved Vegaprol storage conditions. Protect from moisture and keep out of reach of children. Do not use after expiry.

PRESENTATION

Vegaprol Tablets 2.5 mg, 5 mg and 10 mg.
Pack sizes: **14 tablets** and **2 x 10 tablets**, as indicated on the carton.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.