VEGATEN TABLETS

Captopril 25 mg and 50 mg
Oral tablets | Pack size: 2 x 10

COMPOSITION

Each Vegaten 25 mg tablet contains Captopril 25 mg. Each Vegaten 50 mg tablet contains Captopril 50 mg. Excipients: according to the approved Vegaten formulation.

THERAPEUTIC CLASS

Angiotensin-converting enzyme (ACE) inhibitor; antihypertensive and vasodilator. Medical segments: Cardiology (primary), Internal Medicine and Nephrology.

PHARMACOLOGY

Captopril inhibits conversion of angiotensin I to angiotensin II, reducing vasoconstriction and aldosterone secretion. It lowers blood pressure and reduces cardiac afterload; it may also reduce proteinuria in selected patients.

INDICATIONS

Hypertension; congestive heart failure, usually as part of combination treatment; left ventricular dysfunction after myocardial infarction in clinically stable patients; and diabetic nephropathy in selected patients with type 1 diabetes, according to approved prescribing information.

DOSAGE: HYPERTENSION

Adults: commonly start 25 mg twice or three times daily. If required, increase after 1–2 weeks to 50 mg twice or three times daily according to blood pressure and tolerability. Higher doses or combination therapy require medical supervision. Individualize in patients receiving diuretics or at risk of hypotension.

DOSAGE: HEART FAILURE

Initiate under close medical supervision. In volume-depleted or high-risk patients, 6.25–12.5 mg three times daily may be appropriate; these doses require a suitable lower-strength formulation. Other patients may start 25 mg three times daily. Titrate gradually according to response, blood pressure, kidney function and serum potassium.

POST-MYOCARDIAL INFARCTION

In stable patients with left ventricular dysfunction, treatment may begin as early as 3 days after infarction under specialist supervision, often with an initial 6.25 mg dose, then 12.5 mg three times daily. Titrate to a target of 50 mg three times daily if tolerated. Lower strengths may be needed for initiation.

DIABETIC NEPHROPATHY

A referenced adult regimen is 25 mg three times daily for appropriate patients with diabetic nephropathy. Monitor renal function, serum potassium and blood pressure.

METHOD OF ADMINISTRATION

Take orally approximately 1 hour before meals, as food reduces absorption. Follow the prescribed schedule. If a dose is missed, take it when remembered unless nearly time for the next dose; do not double doses. Do not discontinue without medical advice.

RENAL IMPAIRMENT

Captopril is eliminated mainly by the kidneys. In significant renal impairment, use a lower starting dose, smaller increments and slower titration. Monitor creatinine/eGFR and serum potassium before and during treatment. Dose selection is individualized.

BOXED WARNING: FETAL TOXICITY

When pregnancy is detected, discontinue captopril as soon as possible. Medicines acting on the renin-angiotensin system can cause fetal injury and death, especially in the second and third trimesters. Counsel patients who may become pregnant.

CONTRAINDICATIONS

Hypersensitivity to captopril or another ACE inhibitor; previous ACE inhibitor-associated angioedema; hereditary or idiopathic angioedema. Avoid use with aliskiren in patients with diabetes. Concomitant sacubitril/valsartan is contraindicated; observe the required 36-hour washout.

WARNINGS: ANGIOEDEMA

Angioedema of the face, lips, tongue, throat or intestine can occur at any time and may be fatal. Stop the drug and obtain emergency care for swelling, difficulty breathing or swallowing. ACE inhibitor-related cough may occur.

OTHER WARNINGS AND PRECAUTIONS

Severe hypotension may occur, especially with dehydration, diuretics or heart failure. Hyperkalemia, deterioration of renal function, neutropenia/agranulocytosis and proteinuria have been reported. Use caution with renal artery stenosis and collagen vascular disease; monitor clinically indicated blood tests.

DRUG INTERACTIONS

Potassium supplements, potassium-sparing diuretics, salt substitutes and trimethoprim may raise potassium. NSAIDs may impair kidney function and reduce antihypertensive effect. Lithium toxicity may increase. Other blood pressure medicines and diuretics may cause excessive hypotension. Avoid dual renin-angiotensin blockade unless specialist-directed.

PREGNANCY AND LACTATION

Contraindicated during pregnancy because of fetal toxicity. Small amounts of captopril may enter breast milk; assess infant age, prematurity, treatment necessity and local guidance before use while breastfeeding.

ADVERSE REACTIONS

Cough, dizziness, hypotension, altered taste, rash, itching and gastrointestinal symptoms may occur. Serious reactions include angioedema, hyperkalemia, kidney injury, neutropenia and severe hypotension. Seek prompt medical attention for facial swelling, fainting or signs of infection.

OVERDOSAGE

Marked hypotension may occur. Seek emergency medical care. Treatment is supportive, with attention to blood pressure, fluid status, kidney function and electrolytes.

STORAGE

Store in the original packaging according to Vegaten's approved storage conditions, protected from moisture. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Vegaten Tablets 25 mg: 2 x 10 tablets.
Vegaten Tablets 50 mg: 2 x 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.