SINOPREX TABLETS

(Lisinopril Dihydrate 5 mg, 10 mg & 20 mg)

COMPOSITION

Each Sinoprex 5 mg tablet contains Lisinopril Dihydrate equivalent to Lisinopril 5 mg.

Each Sinoprex 10 mg tablet contains Lisinopril Dihydrate equivalent to Lisinopril 10 mg.

Each Sinoprex 20 mg tablet contains Lisinopril Dihydrate equivalent to Lisinopril 20 mg.

Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Lisinopril is an angiotensin-converting enzyme (ACE) inhibitor. It reduces formation of angiotensin II and decreases aldosterone secretion, thereby lowering vascular resistance and blood pressure. It is active after oral administration and is not significantly metabolised.

INDICATIONS

Treatment of hypertension in adults and eligible paediatric patients; adjunct treatment of heart failure; and treatment of haemodynamically stable patients after acute myocardial infarction to improve survival, subject to locally approved indications.

DOSAGE AND ADMINISTRATION

For oral use, usually once daily, with or without food. Individualise dosage according to indication, blood pressure, renal function, clinical response and tolerability.

Adult hypertension: Usual initial dose 10 mg once daily; titrate according to response. Common maintenance range 20-40 mg daily. When a diuretic cannot be withheld, consider a 5 mg initial dose with medical supervision.

ADDITIONAL DOSAGE GUIDANCE

Heart failure: Initial dose generally 5 mg once daily (2.5 mg may be required in selected patients). Increase gradually as tolerated, up to 40 mg once daily, with careful blood pressure and renal monitoring.

Acute myocardial infarction: In haemodynamically stable adults, 5 mg within 24 hours, 5 mg 24 hours later, then 10 mg after 48 hours and 10 mg once daily thereafter, generally for at least six weeks. Lower doses may be necessary if systolic blood pressure is low. Hospital supervision is required.

Only 5 mg, 10 mg and 20 mg Sinoprex strengths are supplied; if 2.5 mg is prescribed, use an appropriate dosage form.

PAEDIATRIC USE

For hypertension in children aged 6 years and above with adequate renal function, an initial dose of 0.07 mg/kg once daily (maximum initial dose 5 mg) may be used; adjust as clinically indicated. Not recommended in children under 6 years or with GFR below 30 mL/min/1.73 m^2. Specialist guidance is required.

ELDERLY & RENAL IMPAIRMENT

Assess renal function before initiation and during treatment. Reduced starting doses may be needed in renal impairment; some patients require a 2.5 mg strength not included in this presentation. Older patients may be more susceptible to hypotension or kidney-function changes.

CONTRAINDICATIONS

Hypersensitivity to lisinopril or another ACE inhibitor; history of ACE inhibitor-related angioedema; hereditary or idiopathic angioedema; concurrent aliskiren in patients with diabetes; concomitant sacubitril/valsartan or use within 36 hours of switching from/to it. Contraindicated during pregnancy.

WARNINGS & PRECAUTIONS

Fetal toxicity: Medicines acting on the renin-angiotensin system can cause fetal injury and death. Discontinue promptly if pregnancy is detected and seek medical advice.

Angioedema: Swelling of the face, lips, tongue, throat or bowel can occur and may be life-threatening. Stop treatment and seek emergency care, especially if breathing or swallowing is affected.

Hypotension: Symptomatic low blood pressure may occur, particularly with volume depletion, diuretics, heart failure or after myocardial infarction. Correct fluid/salt depletion where appropriate and monitor closely.

Kidney function and potassium: Monitor serum creatinine/eGFR and potassium before and during therapy. Acute kidney injury and hyperkalaemia may occur, particularly with kidney disease, dehydration or interacting medicines.

Other precautions: Persistent dry cough, rare liver injury and severe allergic reactions can occur. Use caution in aortic stenosis and with procedures or therapies that increase anaphylactoid-reaction risk.

DRUG INTERACTIONS

Potassium supplements, potassium-containing salt substitutes and potassium-sparing diuretics increase hyperkalaemia risk. Diuretics may increase first-dose hypotension. NSAIDs may impair kidney function and reduce antihypertensive effect. Lithium toxicity may increase.

Avoid dual renin-angiotensin-system blockade unless specifically supervised. Aliskiren is contraindicated in patients with diabetes. Sacubitril/valsartan requires a 36-hour separation. mTOR inhibitors may increase angioedema risk. Review all medicines with the prescriber.

PREGNANCY & LACTATION

Do not use during pregnancy. Inform the physician immediately if pregnancy occurs or is planned. Breastfeeding is not recommended during treatment; discuss alternatives with a healthcare professional.

ADVERSE REACTIONS

Commonly reported effects include dizziness, headache, persistent dry cough, fatigue and hypotension; nausea or diarrhoea may also occur. Changes in kidney function and increased blood potassium may be detected on blood tests.

Serious reactions include angioedema, marked hypotension, acute kidney injury, severe hyperkalaemia and, rarely, liver injury or serious allergic reactions. Seek immediate medical assistance for facial or throat swelling, breathing difficulty, fainting or severe weakness.

OVERDOSAGE

Overdose may produce marked hypotension, dizziness, shock, electrolyte abnormalities or renal dysfunction. Seek urgent medical care. Management is supportive, with monitoring of blood pressure, kidney function and electrolytes; intravenous fluids may be indicated. Lisinopril can be removed by haemodialysis.

STORAGE CONDITIONS

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

PRESENTATION

Sinoprex Tablets 5 mg: pack of 10 tablets.

Sinoprex Tablets 10 mg: pack of 10 tablets.

Sinoprex Tablets 20 mg: pack of 10 tablets.

All strengths are for oral administration.

PATIENT ADVICE

Take exactly as prescribed, at approximately the same time each day. Do not change the dose or stop treatment without medical advice. Attend blood pressure, renal function and potassium monitoring appointments. Avoid potassium supplements unless advised. Report persistent cough, dizziness or reduced urine output. Seek emergency care for swelling of the face or throat.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.