SIMTIN TABLETS

(Simvastatin 20 mg & 40 mg)

COMPOSITION

Each Simtin 20 mg tablet contains Simvastatin 20 mg. Each Simtin 40 mg tablet contains Simvastatin 40 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Simvastatin is a lipid-lowering agent of the statin class. It is converted to an active beta-hydroxy acid inhibitor of HMG-CoA reductase, the rate-limiting enzyme in cholesterol biosynthesis. It lowers total cholesterol, LDL cholesterol and triglycerides and may raise HDL cholesterol.

INDICATIONS

As an adjunct to diet for primary hyperlipidemia, mixed lipid disorders, hypertriglyceridemia, primary dysbetalipoproteinemia and familial hypercholesterolemia, as appropriate to the patient. In adults at high cardiovascular risk, simvastatin reduces the risk of major coronary events, stroke and revascularization.

DOSAGE & ADMINISTRATION

Administer orally once daily in the evening, with or without food. The usual adult dose is 20-40 mg daily, individualized to LDL-C response, clinical need and interaction risk. The maximum generally recommended dose is 40 mg daily. An 80 mg dose is restricted to established patients tolerating it long-term and must not be newly initiated.

Assess LDL-C as clinically indicated, as early as 4 weeks after starting or changing treatment. Continue dietary and lifestyle measures. If a dose is missed, take it when remembered unless nearly time for the next dose; do not double the dose.

SPECIAL POPULATIONS

In heterozygous familial hypercholesterolemia, use in children 10 years and older under specialist direction. The usual pediatric dose range is 10-40 mg once daily; other strengths may be required for initiation. In severe renal impairment, a lower starting dose such as 5 mg daily may be necessary. Individualize therapy in older adults.

CONTRAINDICATIONS

Hypersensitivity to simvastatin or formulation components; acute liver failure or decompensated cirrhosis; concomitant strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, certain antiviral regimens), cyclosporine, danazol or gemfibrozil.

WARNINGS & PRECAUTIONS

Myopathy / rhabdomyolysis: Simvastatin may cause muscle injury and rarely rhabdomyolysis with renal failure. Risk increases with higher doses, interacting medicines, older age, renal impairment and untreated hypothyroidism. Patients should promptly report unexplained muscle pain, tenderness or weakness, especially with fever or dark urine. Stop treatment if myopathy is suspected and assess creatine kinase and renal function.

Rare immune-mediated necrotizing myopathy has been reported; persistent weakness or raised CK after stopping therapy warrants assessment.

Liver: Consider liver-enzyme testing before initiation and when clinically indicated. Discontinue if serious hepatic injury occurs. Use caution with substantial alcohol consumption. Small rises in blood glucose or HbA1c have been reported.

DRUG INTERACTIONS

Strong CYP3A4 inhibitors markedly increase simvastatin exposure and must not be co-administered. Avoid grapefruit juice in substantial amounts. Do not combine with gemfibrozil, cyclosporine or danazol.

With verapamil, diltiazem or dronedarone, do not exceed simvastatin 10 mg/day. With amiodarone, amlodipine or ranolazine, do not exceed 20 mg/day. Other fibrates, lipid-modifying niacin, colchicine and certain other medications may raise myopathy risk; evaluate each combination.

Simvastatin may alter anticoagulant response with coumarins: check INR before initiation and after dose changes. Monitor digoxin when indicated. Review all prescription, herbal and nonprescription medicines.

PREGNANCY

Simvastatin may cause fetal harm. Discontinue when pregnancy is recognized in most patients and consult the treating physician about individual therapeutic needs. Routine treatment of hyperlipidemia is generally unnecessary during pregnancy.

LACTATION

Breastfeeding is not recommended during treatment owing to potential risk to the infant.

PEDIATRIC USE

Use for heterozygous familial hypercholesterolemia in children aged 10 years or older according to approved pediatric guidance. Safety and effectiveness for other pediatric indications are not established.

PATIENT COUNSELLING

Follow the prescribed diet and treatment schedule. Inform the physician immediately about muscle symptoms, dark urine, jaundice or a suspected pregnancy. Do not discontinue or change the dose without medical advice.

ADVERSE REACTIONS

Commonly reported effects include headache, abdominal pain, constipation, nausea and upper respiratory tract infection. Other reported reactions include myalgia, weakness, dyspepsia and increased liver enzymes.

Serious reactions may include myopathy, rhabdomyolysis, immune-mediated necrotizing myopathy, severe hepatic injury and hypersensitivity reactions including angioedema. Seek medical attention for severe muscle symptoms, jaundice or allergic reactions.

OVERDOSAGE

There is no specific antidote. Provide symptomatic and supportive care. Assess clinical status, muscle injury, hepatic function and renal function as indicated. Dialysis is not expected to significantly enhance removal.

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

Simtin Tablets 20 mg: pack of 10 tablets.
Simtin Tablets 40 mg: pack of 10 tablets.

THERAPEUTIC CLASS

Lipid-modifying agent; HMG-CoA reductase inhibitor (statin).

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.