MODLIP 5/10/20

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for MODLIP [Atorvastatin Calcium Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Serum-cholesterol reducers, HMG-CoA reductase inhibitor.

INDICATION: MODLIP is indicated as an adjunct to diet to reduce elevated total-cholesterol and triglyceride levels in patients with primary hypercholesterolaemia; and mixed dysbetalipoproteinemia type IIa and type IIb.

DOSAGE AND ADMINISTRATION: Hyperlipidemia (Heterozygous Familial and Non familial) and Mixed Dyslipidemia *Fredrickson Types IIa and IIb)*: starting dosage is 10mg or 20mg and can be titrated up to 80mg with/without food; Heterozygous Familial Hypercholesterolemia in Pediatric Patients (10-17 years of age): 10 to 20mg daily; Homozygous Familial Hypercholesterolemia: 10 to 80mg daily.

CONTRAINDICATION: Hypersensitivity to any component of this medication. Active liver disease or unexplained persistent elevations of serum transaminases. Atorvastatin is contra-indicated in pregnancy, in breast feeding mothers and in women of childbearing potential not using adequate contraceptive measures. An interval of one month should be allowed from stopping atorvastatin treatment to conception in the event of planning a pregnancy. Safety and efficacy of atorvastatin in children have not yet been established.

WARNINGS & PRECAUTIONS: Liver dysfunction; cognitive problems (memory loss, confusion); hyperglycemia; renal impairment; skeletal muscle problem (rhabdomyolysis); Exercise caution while concomitant use with cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir): HIV protease inhibitor (lopinavir plus ritonavir): Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir) and HIV protease inhibitors (nelfinavirdue to associated risk of myopathy/rhabdomyolysis; CNS toxicity; patients with stroke/recent transient ischemic stroke.

DRUG INTERACTIONS: Interacts with fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, strong inhibitors of CYP 3A4, clarithromycin, erythromycin, azithromycin, combination of protease inhibitors, diltiazem, ezetimibe, itraconazole, grapefruit juice, cyclosporine, rifampin, inducers of cytochrome P450 3A4, verapamil, amiodarone, gemfibrozil/fibrates, niacin, colchicine, colestipol, antacid, amlodipine, fusidic acid, digoxin, oral contraceptives and warfarin.

ADVERSE REACTIONS: Myopathy, rhabdomyolysis, abdominal pain, constipation, diarrhoea, dyspepsia, nausea, flatulence, nasopharyngitis, hyperglycemia, pharyngolaryngeal pain, epistaxis, arthralgia, pain in extremity, musculoskeletal pain, muscle spasms, myalgia, joint swelling, liver function test abnormal, blood creatine phosphokinase increased, insomnia, headache, asthenia, hepatitis, anorexia, pancreatitis, eructation, thrombocytopenia, allergic reaction, alopecia, hyperglycemia/hypoglycemia, paresthesia, hypoesthesia, peripheral neuropathy, dysgeusia, vision blurred, visual disturbances, cholestasis, hepatic failure, skin rash, urticaria, pruritus, alopecia, angioneurotic oedema, bullous rashes (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, tinnitus, hearing loss, tendon rupture, impotence, gynecomastia, cognitive

impairments, memory loss, confusion, pain (chest/back), malaise, weight gain, peripheral edema, pyrexia, sexual dysfunction, depression, interstitial lung disease, amnesia, forgetfulness.

MARKETED BY:

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(Additional information is available on request)