STL/COD-03/IN/00

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Cod-Atorvastatin®

Atorvastatin Tablets 10mg

Codix Codix Pharma Ltd.

Composition:
Each film coated tablet contains:
Atorvastatin Calcium USP
Eq. to Atorvastatin 10mg.
Excipients q.s.

Clinical Pharmacology
Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. Cholesterol and triglycerides circulate in the bloodstream as part of lipoprotein complexes. With ultracentrifugation, these complexes separate into HDL (high-density lipoprotein), IDL (intermediate-density lipoprotein), LDL (low-density lipoprotein), and VLDL (very-low-density lipoprotein) fractions. Triglycerides (TG) and cholesterol in the liver are incorporated into VLDL and released into the plasma for delivery to peripheral tissues. LDL is formed from VLDL and is catabolized primarily through the high-affinity LDL receptor. Clinical and pathologic studies show that elevated plasma levels of total cholesterol (total-C), LDL-cholesterol (LDL-C), and apolipoprotein B (apo B) promote human atherosclerosis and are risk factors for developing cardiovascular disease, while increased levels of HDL-C are associated with a decreased cardiovascular risk.

Indications
COD-ATORVASTATIN-10 is indicated as an adjunct to diet for reduction of elevated total-cholesterol, LDL-cholesterol, apolipoprotein-B, and triglyceride levels in patients with primary hypercholesterolaemia; mixed dyslipidaemia; and heterozygous familial hypercholesterolaemia.

Contraindications
- with hypersensitivity to the active substance or to any of the Excipients of this medicinal product
- with active liver disease or unexplained persistent elevations of serum transaminases exceeding 3 times the upper limit of normal
- during pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraceptive measures

Drug Interactions
HMG-CoA reductase inhibitors: the risk of myopathy Antacid:
decreased plasma concentrations of atorvastatin approximately 35%
Antipyrine: Because COD-ATORVASTATIN-10 does not affect the pharmacokinetics of antipyrine
Colestipol: Plasma concentrations of atorvastatin decreased approximately 25%
Cholestyramine: No data is available.
Cimetidine: Atorvastatin plasma concentrations and LDL-C reduction were not altered
Digoxin: increased steady-state plasma digoxin concentrations by approximately 20%.
Erythromycin: plasma concentrations of COD-ATORVASTATIN-10 increased approximately 40%
Oral contraceptives: increased AUC values of norethindrone and ethinyl estradiol
Approximately 30% and 20%, respectively.
Warfarin: COD-ATORVASTATIN-10 had no clinically significant effect on prothrombin time when administered to patients receiving combined COD-ATORVASTATIN-10 and warfarin therapy for two weeks. Nevertheless, patients receiving COD-ATORVASTATIN-10 should be closely monitored when COD-ATORVASTATIN-10 is combined with warfarin therapy.
Other Concomitant Therapy: In clinical studies, COD-ATORVASTATIN-10 was used concomitantly with antihypertensive agents and oestrogen replacement therapy without evidence of clinically significant adverse interactions. Interaction studies with specific agents have not been conducted.

Warning & Precautions
COD-ATORVASTATIN-10 should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Active liver disease or unexplained persistent transaminase elevations are contra-indications to the use of COD- ATORVASTATIN-10.

Skeletal Muscle:
Rhabdomyolysis with or without renal impairment has been reported with the use of HMG-CoA reductase inhibitors.
Myalgia has been reported in patients treated with COD-ATORVASTATIN-10, Myopathy, defined as muscle aching or muscle weakness in conjunction with increases in creatine phosphokinase (CPK) values greater than 10 times the upper limit of normal, should be considered in any patient with diffuse myalgias, muscle tenderness or weakness, and/or marked elevation of CPK.
As with other HMG-CoA reductase inhibitors, the risk of myopathy during treatment with COD- ATORVASTATIN-10 is increased with concurrent administration of immunosuppressive drugs, including cyclosporine, fibric acid derivatives, nicotinic acid, azole antifungals or erythromycin.

Adverse Reactions

Diarrhoea, constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, arthralgia, asthenia, insomnia, rash, muscle cramps, myositis, myopathy, paraesthesia, peripheral neuropathy, pancreatitis, hepatitis, cholestatic jaundice, anorexia, vomiting, alopecia, pruritus, impotence, hyperglycaemia and hypoglycaemia.

Overdose
There is no specific treatment for atorvastatin overdosage. In the event of an overdose, the patient should be treated symptomatically, and supportive measures instituted as required. Due to extensive drug binding to plasma proteins, hemodialysis is not expected to significantly enhance atorvastatin clearance.

Dosage & Administration
The dose should be individualised according to baseline LDL-C levels, the goal of therapy, and patient response.
The usual starting dose is 10 mg once a day. Adjustment of dose should be made at intervals of 4 weeks or more. The maximum dose is 80 mg once a day.
To be taken as directed by physician. Identification
Reddish brown coloured round, biconvex, both side plain film coated tablets.

Shelf Life: Indication Box & Alu-Alu blister Strip **Storage**
Do not store above 30°C
Keep medicine out of the reach & Sight of children.

Presentation 10 X 10 Tablets in Alu Alu Blister pack. (Box of 100 Tablets) 3 X 10 Tablets in Alu Alu Blister pack. (Box of 30 Tablets)

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Manufactured By:
STALLION LABORATORIES PVT. LTD.