Avator
Atorvastatin

COMPOSITION
Avator 10 Tablet: Each film coated tablet contains Atorvastatin Calcium USP equivalent to Atorvastatin 10 mg.
Avator 20 Tablet: Each film coated tablet contains Atorvastatin Calcium USP equivalent to Atorvastatin 20 mg.

PHARMACOLOGY
Avator (Atorvastatin) is a selective inhibitor of HMG-CoA reductase. This enzyme is the rate-limiting enzyme responsible for the conversion of HMG-CoA to mevalonate, a precursor of sterols, including cholesterol. Avator (Atorvastatin) lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and increases the number of hepatic LDL receptors on the cell surface for enhanced uptake and catabolism of LDL.

INDICATIONS
Avator (Atorvastatin) is indicated as an adjunct to diet to reduce elevated total cholesterol, LDL cholesterol, apolipoprotein B (Apo-B) and triglycerides levels in following diseases when response to diet and other non-pharmacological measures is inadequate.
1. To reduce total cholesterol and LDL cholesterol in patients with heterozygous and homozygous familial hypercholesterolaemia.
2. To reduce elevated cholesterol and triglycerides in patient with mixed dyslipidemia (Fredrickson Type Ia and Ib).
3. For the treatment of patients with elevated serum triglyceride levels in hypertriglyceridaemia (Fredrickson Type IV)
4. For the treatment of patients with dysbetalipoproteinaemia (Fredrickson Type III)
5. To reduce cardiac ischaemic events in patients with asymptomatic or mild to moderate symptomatic coronary artery disease with elevated LDL-cholesterol level.
6. To reduce total and LDL-cholesterol concentrations patients with hypercholesterolemia associated with or exacerbated by diabetes mellitus or renal transplantation.

DOSAGE AND ADMINISTRATION
- **Primary hypercholesterolaemia and combined hyperlipidaemia,**

Adults: Usually 10 mg once daily; if necessary, may be increased at intervals of at least 4 weeks to max. 80 mg once daily; Child (10-18 years) : Initially 10 mg once daily, increased if necessary at intervals of at least 4 weeks to usual max. 20 mg once daily.
- **Familial hypercholesterolaemia,**

Adults: Initially 10 mg daily, increased at intervals of at least 4 weeks to 40 mg once daily; if necessary, further increased to max. 80 mg once daily (or 40 mg once daily combined with anion-exchange resin in heterozygous familial hypercholesterolaemia); Child (10-18 years) : Initially 10 mg once daily, increased if necessary at intervals of at least 4 weeks to usual max. 80 mg once daily.
- **Prevention of cardiovascular events**

Initially 10 mg once daily adjusted according to response.

CONTRAINDICATIONS
Atorvastatin should not be used in patient with hypersensitivity to any component of this medication. Atorvastatin is contraindicated in active liver disease or unexplained persistent elevations of serum transaminases. It is also contraindicated in patient with history of serious adverse reaction to prior administration of HMG-CoA reductase inhibitors.

WARNING AND PRECAUTION
Liver effects: Liver function tests should be performed before the initiation of treatment and periodically thereafter. Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol or have a history of liver disease. Atorvastatin therapy should be discontinued if markedly elevated CPK levels occur or myopathy is diagnosed or suspected.

SIDE EFFECTS
Atorvastatin is generally well-tolerated. The most frequent side effects related to Atorvastatin are constipation, flatulence, dyspepsia, abdominal pain. Other side effects includes infection, headache, back pain, rash, asthenia, arthralgia, myalgia.

USE IN PREGNANCY AND LACTATION
Atorvastatin is contraindicated in pregnancy and while breast-feeding. Women of child bearing potential should use appropriate contraceptive measures during Atorvastatin therapy. If the woman become pregnant while taking Atorvastatin, it should be discontinued.

USE IN CHILDREN AND ADOLESCENTS
The safety and efficacy of Atorvastatin have not been established in paediatric patients younger than 10 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)

DRUG INTERACTIONS
The risk of myopathy during treatment with Atorvastatin is increased with concurrent administration of cyclosporin, fibric acid derivatives, erythromycin, azole antifungals and niacin. No clinically significant interactions were seen when Atorvastatin was administered with antihypertensives or hypoglycemic agents. Patients should be closely monitored if Atorvastatin is added to digoxin, erythromycin, oral contraceptives, colestipol, antacid and warfarin.

OVERDOSAGE
In the event of an overdose, the patient should be treated symptomatically and supportive measures instituted as required.

STORAGE
Store below 30^{O}C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED
Avator 10 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Avator 20 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.