ATV
Atorvastatin

ATV (Atorvastatin Calcium) is a synthetic lipid-lowering agent. It is a selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis. Atorvastatin reduces total cholesterol (C), low-density lipoprotein (LDL) cholesterol, apolipoprotein (apo-B) and triglycerides (TG) in patients with primary hypercholesterolemia and mixed dyslipidemia.

INDICATIONS

Hypercholesterolemia

ATV (Atorvastatin Calcium) is used to adjacent to diet to reduce elevated total cholesterol, LDL-C, apo B, TG levels and to increase HDL-C in patients' with-

* Primary hyper cholesterolemia (heterozygous familial and non-familial) and mixed dyslipidemia

* Elevated serum TG levels

* Primary dysbetalipoproteinemia

* Homozygous familial hypercholesterolemia as an adjacent to other lipid-lowering treatments or if such treatments are unavailable.

Prevention of cardiovascular disease

* In adult patients with multiple risk factors for coronary heart disease, to reduce the risk of myocardial infarction, stroke, revascularization procedures and angina.

* In patients with type 2 diabetes with multiple risk factors for coronary heart disease, to reduce the risk of myocardial infarction and stroke.

* In patients with coronary heart disease, to reduce the risk of non-fatal myocardial infarction, fatal and non-fatal stroke, revascularization procedures, risk of hospitalization for CHF and angina.

DOSAGE AND ADMINISTRATION

* Primary hypercholesterolemia and combined hyperlipidemia- usually 10 mg once daily; if necessary, may be increased at intervals of at least 4 weeks to maximum 80 mg once daily.

Child 10-17 years - usually 10 mg once daily (limited experience with doses above 20 mg daily)

* Familial hypercholesterolemia - initially 10 mg once daily, increased at intervals of at least 4 weeks to 40 mg once daily; if necessary, further increased to maximum 80 mg once daily (or 40 mg once daily combined with anion-exchange resin in heterozygous familial hypercholesterolemia);

Child 10-17 years - initially 10 mg daily, increased if necessary after at least 4 weeks to 20 mg once daily (limited experience with higher doses)

* Prevention of cardiovascular events in type 2 diabetes, 10 mg once daily.

Note: maximum 10 mg daily with concomitant Cyclosporine, maximum 20 mg daily (or temporarily discontinue Atorvastatin) with concomitant Clarithromycin; maximum 40 mg daily (or temporarily discontinue Atorvastatin) with concomitant Itraconazole.

Patients should be placed on a standard cholesterol-lowering diet before receiving Atorvastatin and should continue on this diet during treatment with Atorvastatin. Atorvastatin can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses should be individualized according to patient's characteristics such as goal of therapy and response. After initiation and/or upon titration of Atorvastatin, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.

SIDE EFFECTS

ATV (Atorvastatin Calcium) is generally well tolerated. Adverse reactions have usually been mild and transient. The most frequent adverse events thought to be related to Atorvastatin were constipation, flatulence, dyspepsia and abdominal pain. Also chest pain, back pain, less commonly anorexia, malaise, weight gain, hypoglycemia, hyperglycemia, tinnitus, rarely cholestatic jaundice, peripheral edema; very rarely taste disturbances, gynaecomastia, hearing loss, Stevens-Johnson Syndrome and toxic epidermal necrolysis.

CONTRAINDICATIONS

ATV (Atorvastatin Calcium) is contraindicated in patients with hypersensitivity to any component of this medication, active liver disease or unexpected persistent elevations of serum transaminases.

PRECAUTIONS

Before instituting therapy with Atorvastatin, an attempt should make to control hypercholesterolemia with appropriate diet, exercise and weight reduction in obese patients and to treat other underlying medical problems.

USE IN PREGNANCY AND LACTATION

ATV (Atorvastatin Calcium) is contraindicated in pregnancy and while breast-feeding. Women of child bearing potential should use appropriate contraceptive measures. If the women become pregnant while taking Atorvastatin, it should be discontinued.

OVERDOSAGE

Specific treatment is not available for Atorvastatin overdosage. If an overdose occurs, the patient should be treated symptomatically and supportive measures instituted, as required. Liver function tests and serum CPK levels should be monitored. Due to extensive drug binding to plasma proteins, haemodialysis is not expected to significantly enhance atorvastatin clearance.

DRUG INTERACTIONS

The risk of myopathy during treatment with HMG-CoA reductase inhibitors is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin or cytochrome P450 3A4 inhibitors (e.g. Cyclosporine, Erythromycin, Clarithromycin and Azole antifungals). Concomitant administration of Atorvastatin with inducers of cytochrome P450 3A4 (e.g. Efavirenz, Rifampin) can lead to variable reductions in plasma concentrations of Atorvastatin. No clinically significant interactions were seen when Atorvastatin was administered with antihypertensives and or hypoglycemic agent. Patients should be closely monitored if Atorvastatin is added to Warfarin, Digoxin, Colestipol, Antacids and Oral contraceptives.

PACKAGING

ATV 10 tablet: Each box contains 3 x 10's tablets in alu-alu blister pack. Each film-coated tablet contains Atorvastatin Calcium INN equivalent to Atorvastatin 10 mg.

ATV 20 tablet: Each box contains 3 x 10's tablets in alu-alu blister pack. Each film-coated tablet contains Atorvastatin Calcium INN equivalent to Atorvastatin 20 mg.

ATV 40 tablet: Each box contains 1 x 10's tablets in alu-alu blister pack. Each film-coated tablet contains Atorvastatin Calcium INN equivalent to Atorvastatin 40 mg.

PHARMACEUTICAL PRECAUTION

Store below 25°C. Protect from light and moisture.

WARNING

Keep out of the reach of children.

DELTA
Manufactured by
Delta Pharma Limited
Kishoreganj, Bangladesh