

Composition

Onvas 10 Tablet: Each film coated tablet contains Atorvastatin Calcium Trihydrate USP equivalent to Atorvastatin 10 mg.

Onvas 20 Tablet: Each film coated tablet contains Atorvastatin Calcium Trihydrate USP equivalent to Atorvastatin 20 mg.

Pharmacology

Atorvastatin is a synthetic lipid-lowering agent. Atorvastatin is an inhibitor of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis.

Indications and usage

- Adjunct to diet to reduce elevated total-C, LDL-C, apo B, and triglycerides (TG) levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia
- As an adjunct to diet for the treatment of patients with elevated serum triglycerides (TG) levels
- The treatment of patients with primary dysbetalipoproteinemia who do not respond adequately to diet
- To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable.
- Prior to initiating therapy with atorvastatin, secondary cause for hypercholesterolemia (e.g. poorly controlled diabetes mellitus, hypothyroidism, nephritic syndrome, dysproteinemia, obstructive liver disease, other drug therapy, and alcoholism) should be identified and treated.

Dose & administration

a) Route of administration: Oral

- Adults: At first, 10 or 20 milligrams (mg) once a day. Some patients may need to start at 40 mg per day. Your doctor may increase your dose as needed. However, the dose is usually not more than 80 mg per day.
- Children 10 to 17 years of age: At first, 10 mg once a day. Your doctor may increase your dose as needed. However, the dose is usually not more than 20 mg per day.
- Children younger than 10 years of age: Use and dose must be determined by your doctor.
- Miss dose of this medicine, take it as soon as possible. However, if it is almost time for next dose, skip the missed dose and go back to regular dosing schedule. Do not double doses. Do not take 2 doses of this medicine if it has been more than 12 hours since you missed your last dose.

Contraindication

Hypersensitivity to any component of this medication. Active liver disease or unexplained persistent elevations of serum transaminases.

Warning & Precaution

Caution should be exercised in patients with history of low blood pressure, serious infection, seizures, electrolyte problems, liver problems, alcohol abuse, any allergy, during pregnancy and breastfeeding. It may cause dizziness, do not drive a car or operate machinery while taking this medication. Avoid alcohol consumption. Follow the diet and exercise program as directed by your physician. Monitor blood cholesterol level and liver functions regularly while taking this medication.

Side effects

Common: Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and transient. In controlled clinical studies of 2502 patients, <2% of patients were discontinued due to adverse experiences attributable to atorvastatin. Some common side effects are joint pain, stuffy nose, sore throat, diarrhea, pain in your arms or legs.

Rare: muscle weakness in your hips, shoulders, neck, and back, trouble lifting your arms, trouble climbing or standing. liver problems, kidney problems.

Use in Special Population

Age and sex: There was no clinically relevant effect of age or sex on the pharmacokinetics of atorvastatin in adults.

Severe renal impairment (not on haemodialysis): Starting dose is 5 mg, not to exceed 10 mg.

Use in pregnancy & Lactation

Since HMG-Co A reductase inhibitors decrease cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol, they may cause fetal harm when administered to pregnant women. Therefore, HMG-Co A reductase inhibitors are contraindicated during pregnancy and in nursing mothers. Atorvastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards. If the patient becomes pregnant while taking this drug, therapy should be discontinued and the patient apprised of the potential hazard to the fetus. Because of the potential for adverse reactions in nursing infants, women taking atorvastatin should not breast-feed.

Use in children & adolescents

See the dose and administration'

Drug Interaction

a) **With medicine:** The risk of myopathy during treatment with drugs of this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, niacin (nicotinic acid), erythromycin, azole antifungals. When atorvastatin and antacid suspension containing magnesium and aluminum hydroxide were co-administered, plasma concentrations of atorvastatin decreased approximately 35%. However, LDL-C reduction was not altered. Plasma concentrations of atorvastatin decreased approximately 25% when colestipol and atorvastatin were co-administered. However, LDL-C reduction was greater when atorvastatin and colestipol were co-administered than when either drug was given alone. When multiple doses of atorvastatin and digoxin were co-administered, steady state plasma digoxin concentrations increased by approximately 20%. Patients taking digoxin should be monitored appropriately. In healthy individuals, plasma concentrations of atorvastatin increased approximately 40% with co-administration of atorvastatin and erythromycin. Co-administration of atorvastatin and an oral contraceptive increased AUC values for norethindrone and ethinylestradiol by approximately 30% and 20%. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin.

b) **With food & others:** While taking atorvastatin, avoid high-fat and high-cholesterol foods as part of your overall treatment. You should avoid large quantities of grapefruit or grapefruit juice, which can increase the risk of serious side effects. Also, avoid excess alcohol use, as this may cause serious liver problems.

Overdose

There is no specific treatment for atorvastatin overdose. 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.

Storage

Store below 30°C. protect from light and moisture. Keep all medicines out of reach of children.

Packing

Onvas 10 Tablet: Each box contains 30 (3x10) tablets in blister pack

Onvas 20 Tablet: Each box contains 20 (2x10) tablets in blister pack.

Manufactured by

ONE PHARMA LTD.

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Bogura, Bangladesh