Only for the use of Medical Professionals

Atasin®

Atorvastatin

Description
Atasin® is a preparation of Atorvastatin which is a lipid-lowering agent. It's 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. 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
Therapy with lipid-altering agents should be only one component of multiple risk factor intervention in individuals at significantly increased risk for atherosclerotic vascular disease due to hypercholesterolemia. Drug therapy is recommended as an adjunct to diet when the response to a diet restricted in saturated fat and cholesterol and other nonpharmacologic measures alone has been inadequate. In patients with CHD or multiple risk factors for CHD, Atasin® can be started simultaneously with diet.

(a) Prevention of cardiovascular disease
(a.1) In adult patients without clinically evident coronary heart disease, but with multiple risk factors for coronary heart disease such as smoking, hypertension, age, low HDL-C [Overweight (*BMI: 25-29 kg/m^2*) or obesity (*BMI:* >30 *kg/m^2*), high carbohydrate intake (>60% of total energy intake), physical inactivity etc.], a family history of early coronary heart disease. Atasin® is indicated to reduce the risk of :

- Myocardial infarction
- Stroke
- Revascularization procedures and angina

(a.2) In patients with type 2 diabetes and without clinically evident coronary heart disease, but with at least one additional risk factor for cardiovascular disease such as retinopathy, albuminuria, smoking, hypertension, age, family history of early CHD etc., Atasin® is indicated to reduce the risk of :

- Myocardial infarction
- Stroke

(a. 3) In patients with clinically evident coronary heart disease, Atasin® is indicated to reduce the risk of :

- Myocardial infarction
- Fatal and non-fatal stroke
- Revascularization procedures
- Hospitalization for CHF
- Angina

(b) Hyperlipidemia
(b.1) As an adjunct to diet to reduce elevated total-C, LDL-C, Apo B, and TG levels and to increase HDL-C patients with primary hypercholesterolemia and mixed dyslipidemia.

(b.2) As an adjunct to diet to reduce total-C, LDL-C, and Apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with an adequate trial of diet therapy the following findings are present :

i. LDL-C remains ≥190 mg/dL or

i i. LDL-C remains ≥160 mg/dL and :

- There is a positive family history of premature cardiovascular disease or
- Two or more other CVD risk factors are present in the pediatric patient

Dosage and administration

Atasin® can be administered as a single dose at any time of the day, with or without food. The starting dose and maintenance doses of Atasin® should be individualized according to patient characteristics such as goal of therapy and response.

The recommended starting dose of Atasin® is 10 or 20 mg once daily. Patients who require a large reduction in LDL-C (more than 45%) may be started at 40 mg once daily, The dosage range of Atasin® is 10 to 80 mg once daily.

After initiation and/or upon titration of Atasin®, lipid levels should be analyzed within 2 to 4 weeks and dosage adjusted accordingly.

Patients with renal impairment

Renal disease does not affect the plasma concentrations nor LDL-C reduction of Atorvastatin; thus, Dosage adjustment in patients with renal Dysfunction is not necessary.

Geriatric use: No overall differences in safety or effectiveness were observed between elderly and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older adults cannot be ruled out. Since advanced age (>65years) is a predisposing factor for myopathy, Atorvastatin should be prescribed with caution in the elderly.

Children and adolescents: Safety and effectiveness in patients 10-17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial of 6 months' duration in adolescent boys and postmenarchal girls. Patients treated with Atorvastatin had an adverse experience profile generally similar to that of patients treated with placebo. Doses greater than 20 mg have not been studied in this patient population.

Atorvastatin has not been studied in controlled clinical trials involving pre-pubertal patients or patients younger than 10 years of age.

Use in pregnancy and lactation

Pregnancy category X. Atorvastatin is contraindicated in women who are or may become pregnant. It is not known whether Atorvastatin is excreted in human milk, but a small amount of another drug in this class does pass into breast milk. Statins have a potential to cause serious adverse reactions in nursing infants, women requiring Atorvastatin treatment should be advised not to nurse their infants.

Side-effects

The most commonly reported adverse reactions in patients treated with Atorvastatin in placebo-controlled trials regardless of causality were: nasopharyngitis, arthralgia, diarrhea, myalgia, pain in extremity, and urinary tract infection.

Contraindications
Atorvastatin is contraindicated in patients who are hypersensitive to any component of this product or to any of its ingredients. It is also contraindicated in patients with active liver disease, which may include unexplained persistent elevations in hepatic transaminase levels.

Precautions
Atorvastatin should be used with caution in patients who consume substantial quantities of alcohol and/ar have a history of liver disease. A history of renal impairment may be a risk factor for the development of rhabdomyolysis. Atorvastatin, like other Statins, occasionally causes myopathy, defined as muscle aches or muscle weakness. The concomitant use of higher doses of Atorvastatin with certain drugs such as cyclosporine and strong CYP3A4 inhibitors (e.g., ctarithromycin, itraconazole, and HIV protease inhibitors increases the risk of myopathy / rhabdomyolysis

Drug Interactions
The risk of myopathy during treatment with Statins is increased with concurrent administration of fibric acid derivatives, lipid-modifying doses of niacin, cyclosporine, or strong CYP3A4 inhibitors (e.g., clarithromycin, rifarnpin, efavirenz, HIV protease inhibitors, and itraconazole).

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

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Atasin ® 10 tablet: Each coated tablet contains Atorvastatin 10 mg as Calcium USP.
Atasin ® 20 tablet: Each coated tablet contains Atorvastatin 20 mg as Calcium USP.
Atasin ® 40 tablet: Each coated tablet contains Atorvastatin 40 mg as Calcium USP.
Atasin ® 80 tablet: Each coated tablet contains Atorvastatin 80 mg as Calcium USP.

Package quantities
Atasin ® 10 tablet: Carton of 30 tablets in blister.
Atasin ® 20 tablet: Carton of 20 tablets in blister.
Atasin ® 40 tablet: Carton of 10 tablets in blister.
Atasin ® 80 tablet: Carton of 12 tablets in blister.
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