Snolip سنولِپ

(Atorvastatin) Tablets USP
10mg, 20mg

(ایٹورواسٹیٹین) ٹیبلیٹس یو ایس پی
۱۰ ملی گرام، ۲۰ ملی گرام

COMPOSITION:
Snolip 10mg Tablet
Each film coated tablet contains:
Atorvastatin……10mg
(as Atorvastatin Calcium Trihydrate)
Finished Product Specs: USP

Snolip 20mg Tablet
Each film coated tablet contains:
Atorvastatin……20mg
(as Atorvastatin Calcium Trihydrate)
Finished Product Specs: USP

MECHANISM OF ACTION:
Atorvastatin is a selective, competitive inhibitor of HMG-CoA reductase, the rate limiting enzyme responsible for the conversion of 3-hydroxy-3-methyl-glutaryl- coenzyme A to mevalonate, a precursor of sterols including cholesterol, Atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL. Atorvastatin reduces total-C, LDL-C, and apo B in patients with homozygous and heterozygous FH, nonfamilial forms of hypercholesterolemia, and mixed dyslipidemia. Atorvastatin also reduces VLDL-C and TG produces variable increases in HDL-C and apolipoprotein A-1.

PHARMACOKINETICS:
Absorption - Atorvastatin is rapidly absorbed after oral administration, maximum plasma concentrations occur within one to two hours. Extent of absorption increases in proportion to atorvastatin dose.

Distribution - Mean volume of distribution of Atorvastatin is approximately 381 Liters. Atorvastatin is 98% bound to plasma proteins. A blood/plasma ratio of approximately 0.25 indicates poor drug penetration into red blood cells.

Metabolism - Atorvastatin is extensively metabolized to ortho and parahydroxylated derivatives and various beta-oxidation products by cytochrome P450 isoenzyme. In vitro inhibition of HMG-CoA reductase by ortho and parahydroxylated metabolites is equivalent to that of Atorvastatin. Approximately 70% of circulating inhibitory activity for HMG-CoA reductase is attributed to active metabolites.

Excretion - Atorvastatin and its metabolites are eliminated primarily in bile following hepatic and/or extra-hepatic metabolism. Mean plasma elimination half-life of atorvastatin in humans is approximately 14 hours, but the half-life of inhibitory activity for HMG-CoA reductase is 20 to 30 hours due to the contribution of active metabolites.

INDICATIONS:
Atorvastatin is indicated as an adjunct to diet for the reduction of elevated cholesterol, LDL-Cholesterol, apolipoprotein B and triglycerides and to increase HDL-cholesterol in patients with primary hypercholesterolemia, heterozygous familial and non-familial hypercholesterolemia, and combined (mixed) hyperlipidemia (Fredrickson types IIa and IIb). Atorvastatin is indicated as an adjunct to diet for the treatment of patients with elevated serum triglyceride levels (Fredrickson type IV) and for the treatment of patients with dysbetalipoproteinemia (Fredrickson type III) who do not respond adequately to diet. Atorvastatin is also indicated for the reduction of total cholesterol and LDL-cholesterol in patients with homozygous familial hypercholesterolemia when response to diet and other non pharmacological measures are inadequate.

CONTRAINDICATIONS:
• Atorvastatin is contraindicated in patients with hypersensitivity to any component of this medication.
• Atorvastatin is also contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases.
• Safety of atorvastatin in pregnancy has not been established, and is contraindicated for use during pregnancy.
• Use of atorvastatin during breast feeding is not recommended, because of the potential for serious adverse effects in nursing infants.

DOSAGE:
The patient should be placed on a standard cholesterol-lowering diet before receiving Snolip and should continue the diet during treatment with Snolip. The usual starting dose is 10 to 80 mg once a day. Dose may be given any time of the day with or without food. Dosage should be individualized according to baseline LDL-C levels, the goal of therapy, and patient response

ADVERSE EFFECTS:
Atorvastatin is generally well tolerated. Adverse reactions have usually been mild and

transient. The most frequent adverse effects associated with Atorvastatin therapy were constipation, flatulence, dyspepsia, abdominal pain, headache, nausea, myalgia, asthenia, diarrhea and insomnia.

PRECAUTIONS:
General - Before instituting therapy with atorvastatin, an attempt should be made to control hypercholesterolemia with appropriate diet, exercise, and weight reduction in obese patients, and to treat other underlying medical problems.

Liver function abnormalities - HMG-CoA reductase inhibitors, like some other lipid lowering therapies, have been associated with biochemical abnormalities of liver function. Liver function tests should be performed before treatment starts, at 6 weeks and 12 weeks after initiation of therapy and any elevation in dose, and periodically thereafter. Liver enzyme changes generally occur in the first three months of treatment with atorvastatin. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. Should a dose-related and reversible increase in serum ALT or AST of >3 times the upper limit of normal persists; reduction of dose or withdrawal of atorvastatin is recommended. The drug should be used with caution in patients who consume substantial quantities of alcohol and/or have past history of liver disease.

Skeletal Muscle - Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy of having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g. severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures). Patients should be advised to report promptly any unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.

Pregnancy Atorvastatin should be administered to women of childbearing age only when such patients are unlikely to conceive and have been inform of the potential hazards. Women of childbearing potential should use adequate contraceptive measures while taking atorvastatin. Pediatric use Treatment experience in a pediatric population is limited to doses of atorvastatin upto 80mg daily for 1 year. No clinical and biochemical abnormalities reported in these patients.

DRUG INTERACTIONS:
Cyclosporine, fibric acid derivatives, erythromycin, azole antifungals or niacin: The risk of myopathy during treatment with drugs belonging to the class of HMG-CoA reductase inhibitors is increased with concurrent administration of these agents. Antacid: Decreased plasma concentrations of atorvastatin may occur when administered along with an oral antacid suspension containing magnesium and aluminium. hydroxides, however LDL-cholesterol reduction is not altered.

Digoxin: When multiple doses of atorvastatin and digoxin were coadminstered steady state plasma digoxin concentrations increased by approximately 20% Patients taking digoxin should be monitored appropriately.

Erythromycin: Plasma concentrations of atorvastatin increased approximately 40% with coadminstration of atrovastatin and erythromycin, a known inhibitor of cytochrome P450.

Oral Contraceptives: Coadministration of atrovastatin and an oral contraceptive increased AUC values for norethindrone and ethinyl estradiol by approximately 30% and 20%. These increases should be considered when selecting an oral contraceptive for a woman taking atorvastatin.

OVERDOSAGE:
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.

STORAGE:
Protect from light & moisture.
Store below 30°C

HOW SUPPLED:
Snolip (Atorvastatin) 10mg is available in alu-alu blister pack of 10 tablets.

Snolip (Atorvastatin) 20mg is available in alu- alu blister pack of 10 tablets.

To be sold on the prescription of a registered medical practitioner only.

Keep all medicines out of the reach of children.

Manufactured by :
Indus Pharma (Pvt.) Ltd.
65/27, Korangi Industrial Area,
Karachi-74900, Pakistan.

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