

COLOSTAT

ATORVASTATIN CALCIUM TRIHYDRATE BP

Compositions:

Colostat 10 Tablet: Each film coated tablet contains Atorvastatin Calcium Trihydrate equivalent to 10mg Atorvastatin. Colostat 20 Tablet: Each film coated tablet contains Atorvastatin Calcium Trihydrate equivalent to 20mg Atorvastatin.

Pharmacology:

Atorvastatin is a selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl- coenzyme A (HMG-CoA) reductase. This enzyme catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis particularly in the liver. By lowering the amount of cholesterol in the liver cells, atorvastatin increases the formation of receptors for LDL, and thereby reduces blood levels of total and LDL cholesterol. In addition to lowering LDL cholesterol, atorvastatin also modestly reduces triglyceride levels and raises HDL (the so-called "good") cholesterol.

Dosage And Administration:

Primary hypercholesterolaemia and combined hyperlipidaemia : Usually 10 mg once daily with/ without food. Familial hypercholesterolaemia : Initially 10 mg daily, increased at intervals of 4 weeks to 40 mg daily.

Contraindications:

Atorvastatin is contraindicated in acute liver disease and in pregnancy & breast feeding mother.

Warning And Precaution:

Should be used with caution in patients with a history of liver disease or with a high alcohol intake. Liver function test should be carried out before and within 1-3 months of starting treatment. Treatment should be discontinued if serum transaminase concentration rises to and persist at 3 times the upper limit of the reference range.

Side Effects:

Reversible myositis(rare), headache, altered liver function tests and gastro-intestinal effects including abdominal pain, nausea and vomiting; also insomnia, angioedema, anorexia, alopecia, impotence, chest pain, hypoglycemia etc.

Use in Pregnancy and Lactation:

Atorvastatin is contraindicated in pregnancy & breast feeding mother.

Drug Interaction:

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:

Specific treatment is not available for atorvastatin overdose. The patient should be treated symptomatically and supportive measures instituted, as required. Liver function tests should be performed and serum CK levels should be monitored. Due to extensive atorvastatin binding to plasma proteins, hemodialysis is not expected to significantly enhance atorvastatin

clearance.

Storage:

Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of the children.

Packing:

Colostat 10 Tablet: Each box contains 5 x 10's tablet in blister strip. Colostat 20 Tablet: Each box contains 3 x 10's tablet in blister strip.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.