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mristati

Tablets

Composition:

Each tablet contains:

Simvastatin

20 mg

Properties:

is a cholesterol-lowering agent which acts through Amristatin inhibition of 3 -hydroxy- 3 methylglutaryl-coenzyme A (HMG-Co A reductase), an enzyme which catalyzes the rate-limiting step of cholesterol biosynthesis.

- Amristatin reduces elevated total cholesterol, low-density lipoprotein (LDL)-cholesterol, and very low density lipoprotein (VLDL) cholesterol concentrations in plasma. It also reduces triglycerides and increases high-density lipoprotein (HDL)-cholesterol concentration in blood

- The hypocholesterolaemic action is exerted through:

Stimulating an increase in LDL-receptors on hepatocyte 1) membranes thereby increasing LDL clearance from the circulation.

2) Inhibition of (HMG-Co A reductase) leading to depletion of intracellular cholesterol.

Pharmacokinetics:

After oral ingestion, 85% of Simvastatin is absorbed from the gastrointestinal tract and is hydrolysed to the active Beta-hydroxyacid form

 Simvastatin undergoes first-pass metabolism in the liver. Less than 5% of an oral dose reaches the circulation as active metabolites. More than 95% of Simvastatin and its active Beta-hydroxyacid metabolite are bound to plasma proteins. The peak plasma concentration is seen in 1 to 2 hours following an oral dose

- Simvastatin is mainly excreted in the faeces via the bile, and about 10-

15% of the metabolites are excreted in the urine.

Indications:

Hypercholesterolaemia particularly type II a and hyperlipoproteinaemias; reducing increased total LDL and VLDLcholesterol levels in plasma.

Prophylactically in hypercholesterolaemic patients as a secondary

prevention of ischaemic heart disease.

Dosage:

The initial dose is 10 mg given as a single dose at night, usual dose is 10-40 mg daily.

The dose may be adjusted at intervals of not less than 4 weeks, to a maximum of 40 mg once daily given at night.

Side effects:

- -The drug is generally well tolerated. However some side effects may include: gastrointestinal disturbances (nausea, flatulence, abdominal pain), headache, dizziness, skin rash, blurred vision, sleep disturbance. - Reversible increase in serum aminotransferases occured in few cases.
- -Myopathy, characterized by myalgia and muscle weakness and associated with increased creatine phosphokinase concentration.

Precautions:

- Liver function tests should be performed before starting treatment with Amristatin and thereafter. The drug should be discontinued if serum trans-aminase levels rise to three times the normal values
- Patients are monitored with creatine phosphokinase measurements; the drug should be stopped if muscle symptoms occur in association with elevated CPK activity.

Drug interactions:

- -Increased risk of myopathy if the drug is taken with immunosuppressive drugs, fibric acid derivatives or nicotinic acid.
 - -Amristatin potentiates the action of coumarin anticoagulants with increase in prothrombin time.

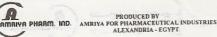
Contra-indications:

- The drug is contraindicated during pregnancy and lactation.
- Acute liver disease or elevated serum transaminases
- Hypersensitivity to any of the components of the drug.

Presentation:

A box containing a strip of 10 tablets.

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