

Composition : Simvastatin 10mg Tablet.

Indications : **Novastin** is indicated for use in patients with primary hypercholesterolemia, in whom response to diet and other non-pharmacological measures has been inadequate. Novastin is also indicated for coronary heart disease and elevated plasma cholesterol levels.

Dosage and administration : The patient should be placed on a standard cholesterol-lowering diet before receiving Novastin and should continue on this diet during treatment with Novastin.

Hypercholesterolemia : The recommended starting dose is 10mg once daily taken in the evening. The dose range is 10 to 40mg a day in single doses taken at night. A marked response to Novastin is seen within two weeks and the maximum therapeutic response occurs within four to six weeks.

Coronary heart disease : Patients with coronary heart disease can be treated with a starting dose of 20mg/day given as a single dose in the evening or as directed by the physician.

Contraindications : Hypersensitivity to any component of this medication ; active liver disease or unexplained persistent elevations of serum transaminases, porphyria, women of childbearing potential unless adequately protected by non-hormonal methods.

Precautions : Novastin should be used with caution in patients who consume substantial quantities of alcohol and/or have a past history of liver disease. Special attention should be paid to patients who develop elevated serum transaminase levels, and in these patients measurements should be repeated promptly and then performed more frequently.

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Drug interactions : Propranolol : In normal volunteers, there was no clinically significant pharmacokinetic or pharmacodynamic interaction with concomitant administration of single doses of Novastin and propranolol.

Digoxin : Concomitant administration of Novastin and digoxin resulted in a slight elevation in drug concentrations in plasma compared to concomitant administration of placebo and digoxin. **Coumarin derivatives :** In patients taking coumarin anticoagulants, prothrombin time should be determined before starting Simvastatin and frequently enough during early therapy to ensure that no significant alteration of prothrombin time occurs. **Other concomitant therapy :** In clinical studies, Novastin was used concomitantly with ACE inhibitors, beta-blockers, calcium antagonists, diuretics and non-steroidal anti-inflammatory drugs without evidence of clinically significant adverse interactions.

Side effects : Novastin is generally well tolerated. Side effects have been usually mild and transient in nature. Abdominal pain, constipation, flatulence, asthenia and headache have been reported. Myopathy has been reported rarely. Other side effects are nausea, diarrhoea, rash, dyspepsia, pruritus, alopecia, dizziness, muscle cramps, myalgia, pancreatitis, paraesthesia, peripheral neuropathy, vomiting and anaemia.

Use in pregnancy and lactation : Pregnancy Category-X. Not for use in pregnancy.

Packing : Novastin : 3 x 10 tablets in blister pack.