Rosucot-F10

Composition: Rosuvastatin 10 + Fenofibrate 160 mg Tablets

Indication: Mixed dyslipidaemia

Mechanism of Action: Rosuvastatin is a selective and competitive inhibitor of HMG-coareductase, the rate-limiting enzyme in cholesterol synthesis. It increases the number of hepatic LDL receptors on the cell surface, enhancing uptake and catabolism of LDL. It also decreases apolipoprotein B, triglycerides and increases HDL. Fenofibrate, a fibric acid derivative, lowers plasma triglyceride by activating lipoprotein lipase thus increasing catabolism of VLDL w/ consequent increase in HDL levels.

Pharmacokinetic's:

Rosuvastatin:

Absorption: Incompletely absorbed from the GI tract. Time to peak plasma concentration: Approx 5 hr. Absolute bioavailability: Approx 20%.

Distribution: Volume of distribution: 134 L. Plasma protein binding: Approx 90%.

Metabolism: Limited metabolism via CYP2C9 isoenzyme. Excretion: Via faeces (approx 90%); urine (approx 5% as unchanged drug). Elimination half-life: Approx 19 hr.

Fenofibrate:

Absorption: Readily absorbed from the GI tract. Increased bioavailabilty w/ food, particularly w/ a high fat meal but is not affected if given as choline salt. Bioavailability: Approx 81% (active metabolite). Time to peak plasma concentration: 2-8 hr.

Distribution: Widely distributed to most tissues. Plasma protein binding: Approx 99% (albumin).

Metabolism: Rapidly hydrolysed to fenofibric acid (active metabolite).

Excretion: Mainly via urine (60% as metabolite); faeces (25%). Elimination half-life: Approx 20 hr.

Side effects:

Rosuvastatin: Headache, dizziness, constipation, nausea, vomiting, abdominal pain, myalgia, chest pain, peripheral oedema, depression, insomnia, rash, paraesthesia, asthenia, abnormal LFT, elevated serum transaminase levels. Potentially Fatal: Severe rhabdomyolysis w/ acute renal failure. Hepatitis, pancreatitis. Rare: Stevens-Johnson syndrome, anaphylaxis, toxic epidermal necrolysis.

Fenofibrate : Abnormal lfts (e.g. Increased ALT, AST), increased creatinine kinase concentrations, abdominal pain, back pain, headache, asthenia, diarrhoea, nausea, constipation, resp disorder, rhinitis, flu syndrome, muscle pain, tenderness or weakness, urticaria, rash. Mild to moderate decreases in Hb, haematocrit and leukocyte counts.Potentially Fatal: Hepatitis, cholecystitis, pancreatitis, rhabdomyolysis.

Rosucot-F10

Precaution:

Rosuvastatin: Patients w/ predisposing factors for myopathy (e.g. Untreated hypothyroidism, renal impairment), history of chronic liver disease and alcoholism. Monitoring Parameters Monitor creatine kinase (CK) periodically and LFT. Discontinue treatment if there is significant or persistent increase in CK levels, serum aminotransferase levels or evidence of myopathy.

Fenofibrate: Increased risk of cholelithiasis, pancreatitis, skeletal muscle effects. Patient at risk of rhabdomyolysis. Renal impairment. Pregnancy. Monitoring Parameters Monitor lfts, renal function and blood cell counts periodically during the 1st 12 mth of therapy.

Dosage:

Adult: Per tablet contains Rosuvastatin 10 mg and fenofibrate (micronised) 160 mg: 1 tablet once daily.