Rosucot-CV10

Composition :
Rosuvastatin 10 mg+ Clopidogrel 75 mg tablets

Indications :
Hyperlipidaemia,Prophylaxis of thromboembolic disorders, Acute coronary syndrome

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.

Clopidogrel selectively inhibits adenosine diphosphate (ADP) from binding to its platelet P2Y12 receptor and subsequent activation of glycoprotein gpiib/iiia complex thus reducing platelet aggregation.

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.
Clopidogrel :

Absorption : Rapidly but incompletely absorbed from the GI tract (approx 50%). Time to peak plasma concentration: Approx 30-60 min.
Distribution : Plasma protein binding: 98% (parent drug); 94% (carboxylic acid derivative).
Metabolism : Undergoes extensive hepatic metabolism via esterase-mediated hydrolysis to inactive carboxylic acid derivative and by CYP450-mediated (primarily CYP2C19 isoenzyme) oxidation to active thiol metabolite.
Excretion : Via urine (approx 50%); faeces (approx 46%) both as metabolites and unchanged drug.

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.

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Clopidogrel : Haematoma, epistaxis, diarrhoea, dyspepsia, abdominal pain, bruising, bleeding at puncture site. Rarely, Stevens-Johnson syndrome, erythema multiforme, serum sickness, interstitial pneumonitis, lichen planus, myalgia. Potentially Fatal: Intracranial bleeding, GI and retroperitoneal haemorrhage, blood dyscrasias, thrombotic thrombocytopenic purpura.

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.

Clopidogrel : Patient at risk of increased bleeding from trauma, surgery or other pathological conditions. Renal and hepatic impairment.Pregnancy and lactation.Monitoring Parameters Monitor for signs of bleeding; Hb and haematocrit periodically.

Dosage :
Rosuvastatin : Adult: PO Hyperlipidaemias; Prophylaxis of CV events in high-risk patients Initial: 5 or 10 mg/day, may increase at 4-wk intervals to 20 mg/day if needed. Max: 40 mg/day.
Clopidogrel : Adult: PO Prophylaxis of thromboembolic disorders 75 mg once daily. Acute coronary syndrome ST-elevation MI: In combination w/ aspirin: 75 mg once daily. Loading dose: 300 mg for patients <75 yr. Continue treatment for at least 4 wk. Unstable angina, non-ST-elevation MI: In combination w/ aspirin: Initial: 300 mg loading dose, followed by 75 mg once daily for up to 12 mth