

CRESLORD 10mg Tablet

(Rosuvastatin Calcium)

DESCRIPTION:

Rosuvastatin, sold under the trade name Creslord among others, is a statin medication, used to prevent cardiovascular disease in those at high risk and treat abnormal lipids. It is recommended to be used together with dietary changes, exercise, and weight loss. It is taken by mouth. The empirical formula is $C_{22}H_{28}FN_3O_6S$ Molecular Weight 481.5 g/mol

COMPOSITION:

Each film coated tablet contains Rosuvastatin calcium Eq. to Rosuvastatin10mg

CLINICAL PHARMACOLOGY:

Pharmacokinetics

Absolute bioavailability of **Rosuvastatin** is about 20% and Cmax is reached in 3 to 5 hours; administration with food did not affect the AUC according to the original sponsor submitted clinical study and as per product label. However, a subsequent clinical study has shown a marked reduction in Rosuvastatin exposure when administered with food. It is 88% protein bound, mainly to albumin. Fraction absorbed of Rosuvastatin is frequently misquoted in the literature as approximately 0.5 (50%) due to a miscalculated hepatic extraction ratio in the original submission package subsequently corrected by the FDA reviewer. It is likely that closer to 0.25 (25%) of the administered dose is absorbed.

Rosuvastatin is metabolized mainly by CYP2C9 and not extensively metabolized; approximately 10% is recovered as metabolite N-desmethyl Rosuvastatin. It is excreted in feces (90%) primarily and the elimination half-life is approximately 19 hours.

Mechanism of Action

Rosuvastatin is a statin with antilipidemic and potential antineoplastic activities. Rosuvastatin selectively and competitively binds to and inhibits hepatic hydroxymethylglutaryl coenzyme A (HMG-CoA) reductase, the enzyme which catalyzes the conversion of HMG-CoA to mevalonate, a precursor of cholesterol. This leads to a decrease in hepatic cholesterol levels and increase in uptake of LDL cholesterol. In addition, Rosuvastatin, like other statins, exhibits pro-apoptotic, growth inhibitory, and prodifferentiation activities in a variety of tumor cell types; these antineoplastic activities may be due, in part, to inhibition of the isoprenylation of Ras and Rho GTPases and related signaling cascades

INDICATION AND USAGE:

Creslord is used along with a proper diet to help lower "bad" cholesterol and fats (such as LDL, triglycerides)

and raise "good" cholesterol (HDL) in the blood. **Creslord** belongs to a group of drugs known as "statins." It works by reducing the amount of cholesterol made by the liver. Lowering "bad" cholesterol and triglycerides and raising "good" cholesterol decreases the risk of disease and helps to prevent strokes and heart attacks. In addition to eating a proper diet (such as a low cholesterol/low-fat diet), other lifestyle changes that may help

this medication work better include exercising, losing weight if overweight, and stopping smoking

DOSAGE AND ADMINISTRATION:

How much you take depends on what you're taking **Creslord** for:

- Preventing heart attacks and strokes - the usual dose for adults is 20mg once a day. Sometimes a lower dose may be prescribed.
- High cholesterol the usual starting dose for adults and children is 5mg to 10mg once a day. If needed, your doctor may increase your dose every 4 weeks up to 20mg a day. The maximum dose for children is 20mg a day. If you have very high cholesterol, you may be prescribed a higher dose of 40mg a day by a specialist. This dosage is not suitable for everyone. Ask your doctor or pharmacist for advice if you're unsure how much to take. Do not reduce your dose without talking to your doctor first.

pregnancy, or breastfeeding. Creslord must not be taken while pregnant as it can cause serious harm to the baby. In the case of breastfeeding, it is unknown whether **Rosuvastatin** is passed through breast milk but, due to the potential of disrupting the infant's lipid metabolism, patients should not breast feed while on **Rosuvastatin**

DRUG INTERACTIONS:

The following drugs can have negative interactions with Creslord and should discuss with the prescribing doctor:

- Coumarin anticoagulants ('blood thinners', e.g. warfarin) can affect the removal of Rosuvastatin
- Cyclosporine, colchicine
- Drugs that may decrease the levels or activity of endogenous steroid hormones, e.g. cimetidine, ketoconazole, and Spironolactone
- Additional medications for high cholesterol such as clofibrate, fenofibrate, gemfibrozil, and niacin (when taken in lipid-modifying doses of 1 g/day and above)
- Specific protease inhibitors including atazanavir (when taken with ritonavir), lopinavir/ritonavir and simeprevir
- Alcohol intake should be reduced while on rosuvastatin in order to decrease risk of developing liver damage
- Aluminum and magnesium hydroxide antacids should not be taken within two hours of taking Rosuvastatin
- Co administration of rosuvastatin with eluxadoline may increase the risk of rhabdomyolysis and myopathy

POSSIBLE SIDE EFFECTS:

Side effects are uncommon. The following side effects should be reported to the prescribing doctor if they persist or get worse:

- Constipation
- Heartburn
- Dizziness
- Sleeplessness
- Depression
- Joint pain
- Cough
- Memory loss or forgetfulness
- Confusion

STORAGE & INSTRUCTIONS:

Keep out of reach of children & Store below 30°C. Protect from sunlight & moisture

Improper storage may deteriorate the medicine

Do not use this medicine after the expiry date which is stated on the blister.

PRESENTATION:

Creslord 10mg tablet in pack of 14'

Manufactured by:



PHARMA LORD

PHARMA LORD | 12km, Lahore
(PVT.)LIMITED | Road Layyah
Pakistan

www.pharma-lord.com