

UNISTAR GOLD / ROZUCOR GOLD

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for UNISTAR GOLD / ROZUCOR GOLD
(Rosuvastatin, Aspirin and Clopidogrel Capsules)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action:

Rosuvastatin: Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor for cholesterol. The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering. Rosuvastatin increases the number of hepatic LDL receptors on the cell-surface, enhancing uptake and catabolism of LDL and it inhibits the hepatic synthesis of VLDL, thereby reducing the total number of VLDL and LDL particles. **Acetylsalicylic acid:** Acetylsalicylic acid inhibits the platelet activation: blocking the platelet cyclooxygenase by acetylation, it inhibits thromboxane A₂ synthesis, a physiological activating substance released by the platelets and which would play a role in the complications of the atheromatous lesions. **Clopidogrel** is a prodrug, one of whose metabolites is an inhibitor of platelet aggregation. Clopidogrel must be metabolised by CYP450 enzymes to produce the active metabolite that inhibits platelet aggregation. The active metabolite of clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet P₂Y₁₂ receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Due to the irreversible binding, platelets exposed are affected for the remainder of their lifespan (approximately 7-10 days) and recovery of normal platelet function occurs at a rate consistent with platelet turnover. Platelet aggregation induced by agonists other than ADP is also inhibited by blocking the amplification of platelet activation by released ADP. Because the active metabolite is formed by CYP450 enzymes, some of which are polymorphic or subject to inhibition by other medicinal products, not all patients will have adequate platelet inhibition.

DOSAGE AND ADMINISTRATION: As directed physician.

CONTRAINDICATION: In patients with hypersensitivity to Rosuvastatin, Clopidogrel and salicylic acid or to any of the excipients, in patients with active liver disease, severe renal and hepatic impairment, myopathy, concomitant combination of sofosbuvir/velpatasvir/voxilaprevir, suffering from gout, Hypothyroidism. [Refer Prescribing information for more details]

WARNINGS & PRECAUTIONS: **Rosuvastatin:** Renal Effects: Proteinuria, detected by dipstick testing, Skeletal Muscle Effects: myalgia, myopathy and, rarely, rhabdomyolysis, Liver Effects: In patients with secondary hypercholesterolaemia caused by hypothyroidism or nephrotic syndrome, the underlying disease should be treated prior to initiating therapy with Rosuvastatin, Lactose Intolerance, Interstitial Lung Disease, Diabetes Mellitus. **Aspirin** may also precipitate bronchospasm or induce attacks of asthma in susceptible subjects or promote other hypersensitivity reactions. Steven-Johnsons syndrome. **Clopidogrel:** Bleeding and haematological disorders, Thrombotic Thrombocytopenic Purpura (TTP), Acquired haemophilia, Recent ischaemic stroke, Cytochrome P450 2C19 (CYP2C19), CYP2C8 substrates, Renal and hepatic impairment. [Refer Prescribing information for more details]

DRUG INTERACTION: Effect of co-administered medicinal products on rosuvastatin: it is a substrate for certain transporter proteins including the hepatic uptake transporter OATP1B1

and efflux transporter BCRP, Ciclosporin: During concomitant treatment with Rosuvastatin and ciclosporin, rosuvastatin AUC values were on average 7 times higher than also have interaction with Protease inhibitors, Gemfibrozil and other lipid-lowering products, Cytochrome P450 enzymes, Methotrexate, impairs the renal excretion of digoxin and lithium, should be used with caution in patients who receive concomitant glycoprotein IIb/IIIa inhibitors. Aspirin: Methotrexate, Uricosuric agents, Anticoagulants, Anti-platelet, Antidiabetics, Diuretics and antihypertensive, Digoxin and lithium, NSAIDs, Carbonic anhydrase inhibitors, Antacids and adsorbents, Antiemetics, Leukotriene antagonists. Clopidogrel: Oral anticoagulants, Thrombolytics, SSRIs, PPI. [Refer Prescribing information for more details]

ADVERSE REACTIONS: Thrombocytopenia, Hypersensitivity reactions including Angioedema, Pancreatitis, Myopathy (including myositis). Rhabdomyolysis, Lupus-like syndrome, Muscle rupture, Increased bleeding tendencies, Hyperuricemia. Intracranial haemorrhage. Reduced hearing ability. Rhinitis, dyspnoea, Bronchospasm, asthma attacks. Gastric or duodenal ulcers and perforation, diarrhoea, Steven-Johnsons syndrome, Eye bleeding (conjunctival, ocular, retinal). [Refer Prescribing information for more details]

MARKETED BY:



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(Additional information is available on request)