ROVOR 2.5

To be sold by retail on the prescription of a Specialist only

Abbreviated Prescribing information for ROVOR 2.5 mg (Rivaroxaban tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Rivaroxaban is a highly selective direct factor Xa inhibitor with oral bioavailability. Inhibition of factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombi. Rivaroxaban does not inhibit thrombin (activated factor II) and no effects on platelets have been demonstrated.

INDICATION: Rivaroxaban 2.5 mg tablet, co-administered with Acetylsalicylic acid (ASA) alone or with ASA plus Clopidogrel or Ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients of the tablet. Active clinically significant bleeding. Lesion or condition, if considered to be a significant risk for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. Concomitant treatment with any other anticoagulants, e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, dabigatran etexilate, apixaban, etc.) except under specific circumstances of switching anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter or concomitant treatment of ACS with antiplatelet therapy in patients with a prior stroke or a transient ischaemic attack (TIA). Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C. Pregnancy and breast-feeding.

WARNINGS & PRECAUTIONS: Treatment in combination with other antiplatelet agents, e.g. prasugrel or ticagrelor, has not been studied and is not recommended. Haemorrhagic risk, renal impairment, interaction with other medicinal products viz. azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir), Congenital or acquired bleeding disorders, uncontrolled severe arterial hypertension, vascular retinopathy, Bronchiectasis or history of pulmonary bleeding, Patients with prosthetic valves, antiphospholipid syndrome, Patients with prior stroke and/or TIA, ACS, spinal/epidural anaesthesia or puncture, dermatological reactions. It contains lactose so; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTION: Rivaroxaban interacts when co-administered with CYP3A4 and P-gp inhibitors (viz. azole-antimycotics such as ketoconazole, itraconazole, voriconazole and posaconazole or HIV protease inhibitors, Erythromycin), anticoagulants (enoxaparin), NSAIDs/platelet aggregation inhibitors (Clopidogrel), SSRIs/SNRIs, warfarin, and CYP3A4 inducers (e.g. phenytoin, carbamazepine, phenobarbital or St. John's Wort (Hypericum perforatum)), Other concomitant therapies when co-administered with midazolam (substrate of CYP3A4), digoxin (substrate of P-gp), atorvastatin (substrate of CYP3A4 and P-gp) or omeprazole (proton pump inhibitor).

ADVERSE REACTIONS: Anaemia, thrombocytosis, allergic reaction, dermatitis allergic, angioedema and allergic oedema, anaphylactic shock, cerebral and intracranial haemorrhage,

syncope, eye haemorrhage, tachycardia, hypotension, haematoma, epistaxis, haemoptysis,gingival bleeding, gastrointestinal tract haemorrhage, gastrointestinal and abdominal pains, dyspepsia, nausea, constipation, hepatic impairment, increased bilirubin, increased blood alkaline phosphatase, increased GGT, jaundice, cholestasis, pruritus, rash, ecchymosis, cutaneous and subcutaneous haemorrhage, Stevens-Johnson syndrome/ toxic epidermal necrolysis, DRESS syndrome, urogenital tract haemorrhage, pain in extremity, renal failure/acute renal failure secondary to bleeding sufficient to cause hypoperfusion, menstrual bleeding may be intensified and/or prolonged, fever, and peripheral oedema.

Marketed BY:
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(Additional information is available on request)