

## ROVOR 10/15/20

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

Abbreviated Prescribing information for ROVOR 10/15/20 mg (Rivaroxaban tablets)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://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.

**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, 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. Clinically relevant bleeding risk including hepatic disease associated with coagulopathy, cirrhotic patients with Child Pugh B and C, and in pregnancy and breast-feeding.
- 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.)

**WARNINGS & PRECAUTIONS:** 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, non-valvular atrial fibrillation who undergo PCI with stent placement, haemodynamically unstable PE patients or patients who require thrombolysis or pulmonary embolectomy, 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*)).

**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

necrosis, 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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**IN/ ROVOR 10/15/20 mg/SEP-20/01/ABPI**

(Additional information is available on request)