

Rivarox[®]

Rivaroxaban INN film coated tablet

DESCRIPTION

Rivarox[®] is a preparation of Rivaroxaban. Rivaroxaban is a selective inhibitor of FXa. It does not require a cofactor (such as Anti-thrombin III) for activity. Rivaroxaban inhibits free FXa and prothrombinase activity. Rivaroxaban has no direct effect on platelet aggregation, but indirectly inhibits platelet aggregation induced by thrombin. By inhibiting FXa, Rivaroxaban decreases thrombin generation.

INDICATIONS

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. **10 Tablet:** Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. **15 mg / 20 mg Tablet:** Prevention of stroke & systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors such as congestive heart failure, hypertension, age \geq 75, diabetes mellitus, prior stroke or transient ischaemic attack (SPAF). Treatment of deep vein thrombosis (DVT) & pulmonary embolism (PE), & prevention of recurrent DVT & PE in adults.

DOSAGE AND ADMINISTRATION

Acute Coronary Syndrome (ACS)

2.5 mg orally twice daily; patients should also take a daily dose of 75 – 100 mg ASA or a daily dose of 75 – 100 mg ASA in addition to either a daily dose of 75 mg Clopidogrel or a standard daily dose of Ticlopidine. Start **Rivarox[®]** as soon as possible after stabilization, including revascularization for ACS; at the earliest 24 hours after admission & at discontinuation of parenteral anticoagulation. If dose is missed take next dose, do not double the dose.

Nonvalvular Atrial Fibrillation:

- ▶ For patients with CrCl >50 mL/min: 20 mg orally, once daily with the evening meal.
- ▶ For patients with CrCl 15 - 50 mL/min: 15 mg orally, once daily with the evening meal.

Treatment of DVT, PE, and Reduction in the Risk of Recurrence of DVT and of PE:

15 mg orally twice daily with food for the first 21 days for the initial treatment of acute DVT or PE. After the initial treatment period, 20 mg orally once daily with food for the remaining treatment and the long-term reduction in the risk of recurrence of DVT and of PE.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery:

10 mg orally, once daily with or without food.

CONTRAINDICATIONS

- ▶ Active pathological bleeding
- ▶ Severe hypersensitivity reaction

WARNINGS AND PRECAUTIONS

- ▶ Risk of bleeding: Rivaroxaban can cause serious and fatal bleeding. Promptly evaluate signs and symptoms of blood loss.
- ▶ Pregnancy-related hemorrhage: Use Rivaroxaban with caution in pregnant women due to the potential for obstetric hemorrhage and/or emergent delivery. Promptly evaluate signs and symptoms of blood loss.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate or well-controlled studies of Rivaroxaban in pregnant women, and dosing for pregnant women has not been established. Use Rivaroxaban with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible.

It is not known if Rivaroxaban is excreted in human milk. Rivaroxaban and/or its metabolites were excreted into the milk of rats. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Rivaroxaban, a decision should be made whether to discontinue nursing or discontinue Rivaroxaban, taking into account the importance of the drug to the mother.

SIDE EFFECTS

- ▶ Hemorrhage
- ▶ Wound secretion
- ▶ Pain in extremity
- ▶ Pruritus

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Rivarox[®] 2.5 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Rivaroxaban INN 2.5 mg.

Rivarox[®] 10 Tablet: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Rivaroxaban INN 10 mg.

Rivarox[®] 15 Tablet: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Rivaroxaban INN 15 mg.

Rivarox[®] 20 Tablet: Box containing 2 strips of 10 tablets each. Each film coated tablet contains Rivaroxaban INN 20 mg.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

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