

RivaXaTM

Rivaroxaban

COMPOSITION

RivaXaTM 2.5 Tablet: Each film-coated tablet contains Rivaroxaban INN 2.5 mg.

RivaXaTM 10 Tablet: Each film-coated tablet contains Rivaroxaban INN 10 mg.

PHARMACOLOGY

Rivaroxaban is a highly selective direct factor Xa inhibitor. Inhibition of factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibits thrombin formation. Rivaroxaban does not inhibit thrombin (activated factor II) and no effects on platelets have been demonstrated.

INDICATION

Rivaroxaban 2.5 mg:

For the prevention of atherothrombotic events in adult patients after an Acute Coronary Syndrome (ACS) with elevated cardiac biomarkers (Troponin or CK-MB). It is co-administered with Aspirin alone or with Aspirin plus Clopidogrel or Ticlopidine.

Rivaroxaban 10-20 mg:

- To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- Deep Vein Thrombosis (DVT) & Pulmonary Embolism (PE) and reduction in the risk of recurrence of DVT and of PE
- For the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery

DOSAGE AND ADMINISTRATION

Rivaroxaban 2.5 mg:

The recommended dose is 2.5 mg twice daily. Patients should also take a daily dose of 75-100 mg Aspirin or a daily dose of 75-100 mg Aspirin in addition to either a daily dose of 75 mg Clopidogrel or a standard daily dose of Ticlopidine.

Rivaroxaban 10-20 mg:

- Nonvalvular Atrial Fibrillation: For patients with Creatinine Clearance >50 mL/min: 20 mg orally, once daily with the evening meal. For patients with Creatinine Clearance 15-50 mL/min: 15 mg orally, once daily with the evening meal
- Treatment of DVT & 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
- Prevention in the risk of recurrence of DVT and of PE: 20 mg once daily with food

- Prophylaxis of DVT following Hip replacement surgery: 10 mg once daily for 35 days
- Prophylaxis of DVT following knee replacement surgery: 10 mg once daily for 12 days

CONTRAINDICATION

Active pathological bleeding & severe hypersensitivity reaction to Rivaroxaban.

PRECAUTIONS

Rivaroxaban can cause bleeding. Promptly evaluate signs and symptoms of blood loss. Rivaroxaban use not recommended in case of Prosthetic heart valves.

SIDE EFFECT

The most common adverse reaction is bleeding. Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation.

DRUG INTERACTION

CYP3A4, P-GP inhibitors and NSAIDs.

USE IN PREGNANCY AND LACTATION

There are no adequate or well-controlled studies of Rivaroxaban in pregnant women and dosing for pregnant women has not been established.

Safety and efficacy of Rivaroxaban have not been established in breast-feeding women.

STORAGE CONDITION

Protect from light, store below 30° C. Keep out of reach of children.

HOW SUPPLIED

RivaXaTM 2.5 Tablet: Each box contains 20 film coated tablets in blister pack.

RivaXaTM 10 Tablet: Each box contains 10 film coated tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH