Rivaban®

Rivaroxaban

Description

Rivaban® is a preparation of Rivaroxaban which is a selective inhibitor of clotting factor Xa (FXa). It does not require a cofactor (such as Anti-thrombin III) for activity. Rivaroxaban inhibits free FXa and prothrombinase activity. Rivaroxaban indirectly inhibits platelet aggregation induced by thrombin. By inhibiting FXa, Rivaroxaban decreases thrombin generation.

Indications

Rivaban® is indicated for -

- Prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
- Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE) and reduction in the risk of recurrence of DVT and of PE
- Prophylaxis of DVT, which may lead to PE in patient undergoing knee or hip replacement surgery
- Prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers

Dosage and administration

Reduction in risk of stroke in nonvalvular atrial fibrillation: 20 mg or 15 mg once daily with the evening meal.

Treatment of DVT or PE: 15 mg twice daily with food, for first 21 days then 20 mg once daily with food.

Reduction in the Risk of Recurrence of DVT and of PE: 20 mg once daily with food.

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

Prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers: 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.

Use in pregnancy & lactation

Pregnancy

Rivaroxaban is pregnancy category C drug. There are no adequate or well-controlled studies of Rivaroxaban in pregnant women, and dosing for pregnant women has not been established.

Lactation

It is not known if Rivaroxaban is excreted in human milk. Safety and efficacy of Rivaroxaban has not been established in breast-feeding women.

Side effects

The most common side effects of Rivaroxaban are increased chance of bleeding, spinal or epidural hematoma and increased risk of stroke after discontinuation in nonvalvular atrial fibrillation.

Contraindications

It is contraindicated in patients with known hypersensitivity of Rivaroxaban or any of the excipients of the product. It is also contraindicated in patients with active pathological bleeding.

Precautions

Early discontinuation of Rivaroxaban, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. Rivaroxaban increases the risk of bleeding that can be fatal in presence of following risk factors- bleeding disorders, uncontrolled severe arterial hypertension, gastrointestinal disease (e.g., inflammatory bowel disease, oesophagitis, gastritis and gastroesophageal reflux disease), vascular retinopathy, bronchiectasis, history of pulmonary bleeding. Signs or symptoms of neurological impairment should be monitored in case of neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture as epidural or spinal hematoma can occur. Rivaroxaban is not recommended in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

Drug interactions

Concomitant use with drugs that are combined P-gp and CYP3A4 inhibitors (ketoconazole, ritonavir, clarithromycin, erythromycin, fluconazole, diltiazem, verapamil, dronedarone) increases in Rivaroxaban exposure and pharmacodynamic effects (i.e., factor Xa inhibition and PT prolongation), that's why should be avoided. Co-administration of Rivaroxaban with a combined P-gp and strong CYP3A4 inducer (e.g., rifampicin, phenytoin, carbamazepine) decreases efficacy of Rivaroxaban and also should be avoided. The concomitant use of other drugs like anti-platelet agents, heparin, fibrinolytic therapy, NSAIDs may cause increased risk of bleeding.

Overdose

Overdose of Rivaroxaban may lead to hemorrhage. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. A specific antidote for Rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of Rivaroxaban overdose may be considered. Partial reversal of laboratory anticoagulation parameters may be achieved with use of plasma products.

Pharmaceutical precautions

Store in a cool (below 30°C) & dry place protected from light. Keep away from the reach of children.

Presentation

Rivaban® 2.5 tablet: Each coated tablet contains Rivaroxaban INN 2.5 mg.
Rivaban® 10 tablet: Each coated tablet contains Rivaroxaban INN 10 mg.
Rivaban® 20 tablet: Each coated tablet contains Rivaroxaban INN 20 mg.

Package quantities

Rivaban® 2.5 tablet: Carton of 30 tablets in blister pack.
Rivaban® 10 tablet: Carton of 20 tablets in blister pack.
Rivaban® 20 tablet: Carton of 20 tablets in blister pack.

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ACI Limited
Godnyl, Narayanganj, Bangladesh