Kinexa®

Rivaroxaban

Tablet

Description

Rivaroxaban is an anticoagulant and the first orally active 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.

Indications

Rivaroxaban is indicated for the prevention of venous thromboembolic events (VTE) in patients who have undergone total hips and knee replacement surgery; prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE); to reduce risk of recurrent DVT and/or PE.

Rivaroxaban is also indicated, in combination with aspirin, for reducing the risk of major cardiovascular events in patients with chronic coronary artery disease or peripheral artery disease.

Dosage and Administration

Nonvalvular Atrial Fibrillation:

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

For patients with CrCl ≤50 mL/min: 15 mg orally, once daily with the evening meal.

Treatment of DVT and/or PE: 15 mg orally twice daily with food for the first 21 days followed by 20 mg orally once daily with food for the remaining treatment.

Reduction in the Risk of Recurrence of DVT and/or PE in patients at continued risk for DVT and/or PE: 10 mg once daily with or without food, after at least 6 months of standard anticoagulant treatment.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery: 10 mg orally once daily with or without food.

Prophylaxis of VTE in Acutely Ill Medical Patients at Risk for Thromboembolic Complications Not at High Risk of Bleeding: 10 mg once daily, with or without food, in hospital and after hospital discharge for a total recommended duration of 31 to 39 days.

Reduction of Risk of Major Cardiovascular Events (CV Death, MI, and Stroke) in chronic CAD or PAD: 2.5 mg orally twice daily, with or without food, in combination with aspirin (75-100 mg) once daily.

Contraindications

Rivaroxaban is contraindicated in patients with active pathological bleeding and severe hypersensitivity reaction to Rivaroxaban (e.g., anaphylactic reactions).

Warnings and Precautions

Risk of Bleeding: Rivaroxaban can cause serious and fatal bleeding. Promptly evaluate signs and symptoms of blood loss and to reverse the anti-factor Xa activity by using antidote with the suggestion of physicians.

Patients with Renal Impairment: Avoid or adjust dose based on CrCl and recommendation by the physician.

Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment. Avoid use of Rivaroxaban in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy since drug exposure and bleeding risk may be increased.

Use with P-gp and Strong CYP3A Inhibitors or Inducers: Avoid concomitant use of Rivaroxaban with known combined P-gp and strong CYP3A inhibitors. Avoid concomitant use of Rivaroxaban with drugs that are known combined P-gp and strong CYP3A inducers.

Patients with Prosthetic Heart Valves: The safety and efficacy of Rivaroxaban have not been studied in patients with prosthetic heart valves. Therefore, use Rivaroxaban is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of Rivaroxaban is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

Side Effects

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

Use in Specific Populations

Pregnancy & Lactation: It is not recommended during pregnancy & lactation. It can be used only if the potential benefit justifies the potential risk to the mother and fetus.

Children & adolescents: The safety and efficacy of Rivaroxaban have not been established in children less than 18 years of age. Therefore, it is not recommended for this group of patients.

Drug Interactions

The use of Rivaroxaban is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (e.g. ritonavir). These active substances are strong inhibitors of both CYP3A4 and P-gp and therefore may increase rivaroxaban plasma concentrations to a clinically relevant degree (2.6 fold on average) which may lead to an increased bleeding risk.

Care is to be taken if patients are treated concomitantly with medicinal products affecting haemostasis such as non-steroidal anti-inflammatory medicinal products (NSAIDs), acetylsalicylic acid and platelet aggregation inhibitors or selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs). For patients at risk of ulcerative gastrointestinal disease an appropriate prophylactic treatment may be considered.

Overdose

Overdose of Rivaroxaban may lead to hemorrhage. Discontinue Rivaroxaban and initiate appropriate therapy if bleeding complications associated with overdosage occur. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption in case of rivaroxaban overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not dialyzable. Partial reversal of laboratory anticoagulation parameters may be achieved with use of plasma products.

For life-threatening or uncontrolled bleeding an antidote is available, patient can use it with the suggestion of physicians.

Pharmaceutical Precautions

Keep in a dry place & store below 30° C. Protect from light & keep out of the reach of children.

Commercial Pack

Kinexa® 2.5 tablet: Box containing 30 tablets in 3 x10's Alu-Alu form packs. Each film coated tablet contains Rivaroxaban INN 2.5 mg.

Kinexa® 10 tablet: Box containing 30 tablets in 3 x10's Alu-Alu form packs. Each film coated tablet contains Rivaroxaban INN 10 mg.

Kinexa® 15 tablet: Box containing 20 tablets in 2 x10's Alu-Alu form packs. Each film coated tablet contains Rivaroxaban INN 15 mg.

Kinexa® 20 tablet: Box containing 20 tablets in 2 x10's Alu-Alu form packs. Each film coated tablet contains Rivaroxaban INN 20 mg.

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