Rivalto®

Rivaroxaban

F.C.Tablet

CATEGORY
Anticoagulant

DESCRIPTION:
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Rivaroxaban for a condition for which it was not prescribed. Do not give Rivaroxaban to other people, even if they have the same condition. It may harm them. This Medication Guide summarizes the most important information about Rivaroxaban. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Rivaroxaban that is written for health professionals.

MECHANISM OF ACTION:
Rivaroxaban is an orally bioavailable factor Xa inhibitor that selectively blocks the active site of factor Xa and does not require a cofactor (such as Anti-thrombin III) for activity. Activation of factor X to factor Xa (FXa) via the intrinsic and extrinsic pathways plays a central role in the cascade of blood coagulation.

INDICATIONS:
- Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation
- Treatment of Deep Vein Thrombosis
- Treatment of Pulmonary Embolism
- Reduction in the Risk of Recurrence of Deep Vein Thrombosis and of Pulmonary Embolism
- Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery

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

PREGNANCY & LACTATION:
- FDA 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.

WARNING & PRECAUTION:
Risk-benefit should be considered when the following medical problems exist:
- Increased Risk of Stroke after Discontinuation in Nonvalvular Atrial Fibrillation; Discontinuing Rivaroxaban in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from Rivaroxaban to warfarin in clinical trials in atrial fibrillation patients. If Rivaroxaban must be discontinued for a reason other than pathological bleeding, consider administering another anticoagulant.
- Risk of Bleeding; Rivaroxaban increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe Rivaroxaban to patients at increased risk of bleeding.
- Spinal/Epidural Anesthesia or Puncture; When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis. An epidural catheter should not be removed earlier than 18 hours after the last administration of Rivaroxaban. The next Rivaroxaban dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of Rivaroxaban is to be delayed for 24 hours.
- Use in Patients with Renal Impairment;
► Nonvalvular Atrial Fibrillation: Avoid the use of Rivaroxaban in patients with CrCl <15 mL/min since drug exposure is increased.
► Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of Rivaroxaban in patients with CrCl <30 mL/min
► Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of Rivaroxaban in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on Rivaroxaban should discontinue the treatment.
- Use in 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.

SIDE EFFECTS
Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:
► Unexpected bleeding or bleeding that lasts a long time, such as:
o nose bleeds that happen often
o unusual bleeding from the gums
o menstrual bleeding that is heavier than normal or vaginal bleeding
o bleeding that is severe or you cannot control
o red, pink or brown urine
o bright red or black stools (looks like tar)
o cough up blood or blood clots
o vomit blood or your vomit looks like “coffee grounds”
o headaches, feeling dizzy or weak
o pain, swelling, or new drainage at wound sites
► Spinal or epidural blood clots (hematoma);
- People who take a thin tube called an epidural catheter is placed in their back to give you certain medicine.
- you take NSAIDs or a medicine to prevent blood from clotting

DOSAGE & ADMINISTRATION:
You should follow the doses and instructions given by your doctor .
General dosing information:
- The 15 mg and 20 mg Rivaroxaban tablets should be taken with food, while the 10 mg tablet can be taken with or without food.

Reduction in risk of stroke in Nonvalvular Atrial Fibrillation	CrCl >50 mL/min: 20 mg once daily with the evening meal
	CrCl= 15 to 50 mL/min: 15 mg once daily with the evening meal
Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE)	15 mg taken orally twice daily with food for the first 21 days; **After 21 days, transition to:** 20 mg taken once daily with food, at approximately the same time each day, for remaining treatment
Reduction in the Risk of Recurrence of DVT and of PE	20 mg taken once daily with food, at approximately the same time each day
Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery	Hip replacement: 10 mg taken orally once daily with or without food, for 35 days; The initial dose should be taken at least 6 to 10 hours after surgery once homeostasis has been established.
	Knee replacement: 10 mg taken orally once daily with or without food, for 12 days; The initial dose should be taken at least 6 to 10 hours after surgery once homeostasis has been established.

Discontinuation for Surgery and other Interventions:
If anticoagulation must be discontinued to reduce the risk of bleeding with surgical or other procedures, Rivaroxaban should be stopped at least 24 hours before the procedure to reduce the risk of bleeding. In deciding whether a procedure should be delayed until 24 hours after the last dose of Rivaroxaban, the increased risk of bleeding.

Missed Dose:
If a dose of Rivaroxaban is not taken at the scheduled time, administer the dose as soon as possible on the same day as follows:
o For patients receiving 15 mg twice daily: The patient should take Rivaroxaban immediately to ensure intake of 30 mg Rivaroxaban per day. In this particular instance, two 15 mg tablets may be taken at once. The patient should continue with the regular 15 mg twice daily intake as recommended on the following day.
o For patients receiving 20, 15 or 10 mg once daily: The patient should take the missed Rivaroxaban dose immediately.

DRUG INTERACTION:
- Rivaroxaban is a substrate of CYP3A4/5, CYP2J2, and the P-gp and ATP-binding cassette G2 (ABCG2) transporters. Inhibitors and inducers of these CYP450 enzymes or transporters (e.g., P-gp) may result in changes in rivaroxaban exposure.
- Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems; (ketoconazole, ritonavir, clarithromycin, erythromycin and fluconazole),(e.g.
- Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems; (e.g., rifampicin, phenytoin) Avoid concomitant use of Rivaroxaban with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John’s wort).
- Anticoagulants and NSAIDs/Aspirin; Avoid concurrent use of Rivaroxaban with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.
- Drug-Disease Interactions with Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems; in Patients with renal impairment (e.g., amiodarone, diltiazem, verapamil, quinidine, felodipine, erythromycin, and azithromycin)

STORAGE:
- Store below 30°C, protect from moisture and light.
- Keep out of the reach of children.

PACKAGING & STRENGHTS AVAILABLE:
- 3 blisters pack of 10 F.C. tablets (10 mg) with a brochure in a cardboard box.
- 3 blisters pack of 10 F.C. tablets (15 mg) with a brochure in a cardboard box.
- 3 blisters pack of 10 F.C. tablets (20 mg) with a brochure in a cardboard box.

• REFERENCES:

- EMC (Electronic Medicines Compendium)

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OSVE

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Date: **99/02/01** **Navaei**

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