Varox-10 Tablet

DRUG INTERNATIONAL LTD.

Composition : Each film coated tablet contains Rivaroxaban INN 10 mg.

Description : Rivaroxaban in highly selective direct factor Xa inhibitor, inhibition of factor Xa interrupts the intrinsic and extrinsic pathway of the blood coagulation cascade, inhibiting both thrombin formation and development of thrombin. Oral absorption of Rivaroxaban is almost complete and oral bioavailability is close to 100% for tablet dose. Plasma protein binding 92% to 95% (primarily to albumin). Rivaroxaban metabolised via CYP3A4, CYP2J2 and CYP. It's eliminated via renal route 33% active substance, 33% inactive substance and faecal route (33%).

Indications : Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery. Treatment of DVT, PE & extended treatment of prevention of recurrent DVT & PE in adult. Reduction in Risk of Stroke & Systemic Embolism in Non valvular Atrial Fibrillation.

Dosage and administration :

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
Reduction in the Risk of Recurrence of DVT and of PE	20 mg once daily with food	
Treatment of DVT, PE & extended treatment of prevention of recurrent DVT & PE in adult.	15 mg twice daily with food, for first 21 days ▼ after 21 days, transition to ▼ 20 mg once daily with food, for remaining treatment	
Reduction in Risk of Stroke & Systemic Embolism in Non valvular 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

Or, as directed by the registered physicians.

Side effects : Adverse reactions of Rivaroxaban may be associated with an increased risk of occult or overt bleeding from any tissue or organ which may result in post haemorrhagic anaemia.

Contraindication : Rivaroxaban is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients, active pathological bleeding, lesion or condition if considered to be a significant risk for major bleeding.

Precautions : Rivaroxaban is not recommended for use in patients with renal impairment, hepatic impairment, spinal/epidural anesthesia or puncture. This medicine increases the risk of bleeding & can cause serious & fatal bleeding.

Use in Pregnancy and lactation : Pregnancy category C. There is no adequate or well-controlled studies of Rivaroxaban in pregnant women, It should be used with caution in pregnant women only if the potential benefit justifies the potential risk to the mother & fetus. It is not known if Rivaroxaban is excreted in human milk. A decision should be made whether to discontinue nursing or discontinue the drug taking into account the importance of the drug to the mother.

Drug Interactions : Rivaroxaban shows drug interaction with CYP3A4 & P-GP inhibitors, anticoagulants, NSAIDS & platelets aggregation inhibitors.

Storage : Keep the medicine out of reach of children. Store below 30°C away from sunlight, dry & cool place.

Packing : Each box contains 1 x 14's tablets in blister pack.