Varox
Tablet

Composition : Each film coated tablet contains Rivaroxaban INN 2.5 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 2.5 mg 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 subestance, 33% inactive subestance and faecal route (33%).

Indications : The medicine is indicated for the prevention of atherothrombotic events in adult patients after an Acute Coronary Syndrome (ACS) with elevated cardic biomarkers (Troponin or CK-MB). It is co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine.

Dosage and administration : The recommended dose is 2.5 mg twice daily, Patients should also take a daily dose 75-100 mg Aspirin or a daily of 75-100 mg aspirin in addition to either a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine. Treatment with Varox should be started as soon as possible after stabilization of the ACS event; at the earliest 24 hours after admission to hospital & at the time when parenteral anticoagulation therapy would normally be dicontinued. 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 25°C away from sunlight, dry & cool place.

Packing : Each box contains 2 x 14's tablets in blister pack.