BetriXa™

Betrixaban

COMPOSITION

BetriXa™ 40 Capsule: Each capsule contains Betrixaban 40 mg as Betrixaban maleate INN.

BetriXa™ 80 Capsule: Each capsule contains Betrixaban 80 mg as Betrixaban maleate INN.

PHARMACOLOGY

Betrixaban is a 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. Betrixaban inhibits free factor Xa and prothrombinase activity. By directly inhibiting factor Xa, Betrixaban decreases thrombin generation (TG). Betrixaban has no direct effect on platelet aggregation.

INDICATION

Betrixaban is indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness and at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.

DOSAGE & ADMINISTRATION

Recommended Dose:

The recommended dose of Betrixaban is an initial single dose of 160 mg, followed by 80 mg once daily. Daily oral doses should be given at the same time of day with food. The recommended duration of treatment is 35 to 42 days.

Patients with Severe Renal Impairment:

No dose adjustment is needed for mild or moderate renal impairment (CrCl > 30 mL/min). For patients with severe renal impairment (CrCl ≥ 15 to < 30 mL/min) the recommended dose of Betrixaban is an initial single dose of 80 mg followed by 40 mg once daily.

Patients with Hepatic Impairment:

No dose adjustment is required in patients with mild hepatic impairment. Avoid use in patients with moderate to severe hepatic impairment.

CONTRAINDICATION

Betrixaban is contraindicated in patients with active pathological bleeding. It is also contraindicated in patients with severe hypersensitivity reaction to Betrixaban.

PRECAUTION

Risk of Bleeding: Can cause bleeding. Promptly evaluate any signs or symptoms of blood loss.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal/epidural puncture is employed, patients treated with antithrombotic 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. Do not remove an epidural catheter earlier than 72 hours after the last administration of Betrixaban. Do not administer the next Betrixaban dose earlier than 5 hours after the removal of the catheter. If traumatic puncture occurs, delay the administration of Betrixaban for 72 hours.

Severe Renal Impairment: Increase risk of bleeding events.

Concomitant P-gp Inhibitors: Increase risk of bleeding events.

SIDE EFFECTS

Most common adverse reaction is bleeding, epidural or spinal hematoma may develop during spinal/epidural anesthesia or puncture.

DRUG INTERACTION

P-gp Inhibitors: Increase the blood level of Betrixaban.

P-gp Inducers: Decrease the blood level of Betrixaban.

Anticoagulants, Antiplatelets and Thrombolytics: May increase the risk of bleeding.

USE IN PREGNANCY AND LACTATION

Use in Pregnancy: There are no data with the use of Betrixaban in pregnant women, but treatment is likely to increase the risk of hemorrhage during pregnancy and delivery.

Lactation: No data are available regarding the presence of Betrixaban or its metabolites in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.

STORAGE

Protect from light and moisture, store below 30°C. Keep the medicine out of reach of children.

HOW SUPPLIED

BetriXa™ 40 Capsule: Each box contains 10 capsules in blister pack.

BetriXa™ 80 Capsule: Each box contains 10 capsules in blister pack.

Manufactured by

SQUARE

PHARMACEUTICALS LTD.

BANGLADESH