Apixa®

Apixaban
Tablet

Description

Apixa® (Apixaban) is an oral, reversible, and selective active site inhibitor of FXa. It does not require antithrombin III for antithrombotic activity. Apixaban inhibits free and clot-bound FXa, and prothrombinase activity.

Indications

Apixaban is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

Dosage and Administration

Recommended Dose

The recommended dose of Apixaban for most patients is 5 mg taken orally twice daily.

Dosage Adjustments

The recommended dose of Apixaban is 2.5 mg twice daily in patients with any 2 of the following characteristics:

- age ≥80 years
- body weight ≤60 kg
- serum creatinine≥1.5mg/dL

CYP3A4 and P-gp inhibitors: When Apixaban is coadministered with drugs that are strong dual inhibitors of cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) (e.g. ketoconazole, itraconazole, ritonavir, clarithromycin) the recommended dose is 2.5 mg twice daily.

Missed Dose

If a dose of Apixaban is not taken at the scheduled time, the dose should be taken as soon as possible on the same day and twice daily administration should be resumed. The dose should not be doubled to make up for a missed dose.

Discontinuation for Surgery and Other Interventions

Apixaban should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of unacceptable or clinically significant bleeding. Apixaban should be discontinued at least 24 hours prior to elective surgery or invasive procedures with a low risk of bleeding or where the bleeding would be non-critical in location and easily controlled.

Switching from or to Apixaban

Switching from warfarin to Apixaban: Warfarin should be discontinued and Apixaban started when the international normalized ratio (INR) is below 2.0.

Switching from Apixaban to warfarin: Apixaban affects INR, so that INR measurements during co administration with warfarin may not be useful for determining the appropriate dose of warfarin. If continuous anticoagulation is necessary, discontinue Apixaban and begin both a parenteral anticoagulant and warfarin at the time the next dose of Apixaban would have been taken, discontinuing the parenteral anticoagulant when INR reaches an acceptable range.

Switching between Apixaban and anticoagulants other than warfarin: Discontinue one being taken and begin the other at the next scheduled dose.

Hepatic Impairment

No dose adjustment is required in patients with mild hepatic impairment.

Because patients with moderate hepatic impairment may have intrinsic coagulation abnormalities and there is limited clinical experience with Apixaban in these patients, dosing recommendations cannot be provided

Apixaban is not recommended in patients with severe hepatic impairment

Renal Impairment

The dosing adjustment for moderate renal impairment is described above. No data inform use in patients with creatinine clearance <15 ml/min or on dialysis.

Contraindications

Apixaban is contraindicated in patients with the following conditions:

- Active pathological bleeding
- Severe hypersensitivity reaction to Apixaban (i.e. anaphylactic reactions)

Warning and Precautions

Increased Risk of Stroke with Discontinuation of Apixaban

Discontinuing Apixaban in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from Apixaban to warfarin in clinical trials in patients with nonvalvular atrial fibrillation. If Apixaban must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant.

Side Effects

Common side effects are haemorrhage, contusion, epistaxis and haematoma.

Use in Specific Populations

Pregnancy

There are no adequate and well-controlled studies of Apixaban in pregnant women. Treatment is likely to increase the risk of hemorrhage during pregnancy and delivery. Apixaban should be used during pregnancy only if the potential benefit outweighs the potential risk to the mother and fetus.

Labor and Delivery

Safety and effectiveness of Apixaban during labor and delivery have not been studied in clinical trials. Consider the risks of bleeding and of stroke in using Apixaban in this condition.

Nursing Mothers

It is unknown whether Apixaban or its metabolites are excreted in human milk.

Women should be instructed either to discontinue breastfeeding or to discontinue Apixaban therapy, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Of the total subjects in clinical studies of Apixaban, >69% were 65 and older, and >31% were 75 and older. The effects of Apixaban on the risk of stroke and major bleeding compared to warfarin were maintained in geriatric subjects.

Drug interactions

Apixaban is a substrate of both CYP3A4 and P-gp. Inhibitors of CYP3A4 and P-gp increase exposure to Apixaban and increase the risk of bleeding. Inducers of CYP3A4 and P-gp decrease exposure to Apixaban and increase the risk of stroke.

Overdose

There is no antidote to Apixaban. Overdose of Apixaban increases the risk of bleeding. Activated charcoal may be useful in the management of Apixaban overdose.

Pharmaceutical Precautions

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

Commercial Pack

Apixa® 2.5 Tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Apixaban INN 2.5 mg.

Apixa® 5 Tablet: Box containing 20 tablets in 2x10's blister strips. Each film coated tablet contains Apixaban INN 5 mg.

BEXIMCO PHARMA

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