



Apixaban INN

COMPOSITION

Apiban 2.5 Tablet: Each film coated tablet contains Apixaban INN 2.5 mg.

Apiban 5 Tablet: Each film coated tablet contains Apixaban INN 5 mg.

PHARMACOLOGY

Apixaban is a selective inhibitor of Factor Xa. It does not require antithrombin III for antithrombotic activity. It inhibits free and clot-bound Factor Xa, and prothrombinase activity. It indirectly inhibits platelet aggregation induced by thrombin. By inhibiting Factor Xa, it decreases thrombin generation and thrombus development.

INDICATION

For the following cases it is indicated:

- to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.
- for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients who have undergone hip or knee replacement surgery.
- for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and to reduce the risk of recurrent of these.

DOSAGE AND ADMINISTRATION

Reduction of Risk of Stroke and Systemic Embolism in Patients with Nonvalvular Atrial Fibrillation: The recommended initial dose is 5 mg taken orally twice daily. The recommended dose is 2.5 mg twice daily in patients with at least two of the following characteristics:

- Age greater than or equal to 80 years.
- Body weight less than or equal to 60 kg.
- Serum creatinine greater than or equal to 1.5 mg/dL.

Prophylaxis of Deep Vein Thrombosis (DVT) following Hip or Knee Replacement Surgery: The recommended initial dose is 2.5 mg taken orally twice daily (12 to 24 hours after surgery). In patients undergoing hip replacement surgery, the duration of treatment is 35 days. In patients undergoing knee replacement surgery, the duration of treatment is 12 days.

Treatment of DVT and PE: The recommended dose is 10 mg taken orally twice daily for the first 7 days of therapy and after 7 days the dose is 5 mg taken orally twice daily.

Reduction in the Risk of Recurrence of DVT and PE: The recommended dose is 2.5 mg taken orally twice daily after at least 6 months of treatment for DVT or PE.

Missed Dose: If a dose of it 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.

Temporary Interruption for Surgery and Other Interventions: It should be discontinued at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of bleeding. It is usually not necessary to bridge the anticoagulation within 24 to 48 hours of stopping and before the intervention. It should be resumed as soon as adequate hemostasis is achieved after surgery or other procedures.

Switching among anticoagulants:

Switching from Warfarin to Apixaban	Discontinue warfarin and start Apixaban when the international normalized ratio (INR) is below 2.0.
Switching from anticoagulants other than Warfarin (oral or parenteral) to Apixaban	Stop taking anticoagulants other than Warfarin and start taking Apixaban at the normal time to take the next dose.

For patients who are unable to swallow whole tablets: It may be crushed and suspended in water, 5% Dextrose in water, apple juice or mixed with applesauce and promptly administered orally for those who are unable to swallow tablets. If required, it may be crushed and suspended in 60 mL of water or 5% Dextrose in water and promptly delivered through a nasogastric tube. Crushed tablets are stable in water, 5% Dextrose in water, apple juice and applesauce for up to 4 hours.

Paediatric Use: Safety and effectiveness in Paediatric patients have not been established.

Apixaban is not recommended in patients with severe hepatic impairment.

CONTRAINDICATION

It is contraindicated in patients with active pathological bleeding, adverse reactions and severe hypersensitivity reaction to any of the components of it.

WARNING AND PRECAUTION

It can cause serious and potentially fatal bleeding. Promptly evaluate signs and symptoms of blood loss. Patients with prosthetic heart valves are not recommended. Increased risk of thrombosis in patients with triple positive antiphospholipid syndrome are not recommended.

SIDE EFFECTS

Most common side effects (>1%) are related to bleeding.

USE IN PREGNANCY AND LACTATION

Pregnancy: Not recommended.

Lactation: Discontinue drug or discontinue nursing.

DRUG INTERACTION

Combined P-gp and Strong CYP3A4 Inhibitors: Increases blood level of Apixaban. Reduce the dose of Apixaban or avoid coadministration.

Simultaneous use of P-gp and Strong CYP3A4 Inducers: Avoid concomitant use.

OVERDOSAGE

Overdose increases the risk of bleeding. Administration of activated charcoal may be useful in the management of overdose or accidental ingestion.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Apiban 2.5 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

Apiban 5 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.