Name of the medicinal product:

Apiraban® 2.5 & 5 mg Tablet

Therapeutic indications:

- Deep vein thrombosis
- Nonvalvular atrial fibrillation
- Postoperative venous thrombophylaxis following hip or knee replacement surgery
- Pulmonary embolism

Method of administration:

The recommended dose of **Apiraban®** for most patients is 5 mg taken orally twice daily.

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

- Age ≥80 years
- Body weight ≤60 kg
- Serum creatinine ≥ 1.5 mg/dL

Dosage and administration:

Disease	Dose	
Deep vein thrombosis	**Treatment**	**10 mg twice daily for 7 days followed by 5 mg twice daily**
	Recurrence risk reduction	**2.5 mg twice daily after at least 6 month of treatment for DVT**
Pulmonary embolism	**Treatment**	**10 mg twice daily for 7 days followed by 5 mg twice daily**
	Recurrence risk reduction	**2.5 mg twice daily after at least 6 month of treatment for DVT**
Nonvalvular atrial fibrillation (to prevent stroke and systemic embolism)	**5 mg twice daily unless the patient has any 2 of the following: age≥ 80 years, body weight ≤60 kg, serum creatinine ≥1.5 mg/dL, then reduce dose to 2.5 mg twice daily**	
Postoperative venous thrombophylaxis	**hip replacement**	**2.5 mg twice daily beginning 12 to 24 hours postoperatively; duration: 35 days**
	knee replacement	**2.5 mg twice daily beginning 12 to 24 hours postoperatively; duration: 12 days**

PRESCRIBING INFORMATION:

Apiraban®is a factor Xa inhibitor anticoagulant indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. **INDICATIONS:** Deep vein thrombosis, Pulmonary embolism, Nonvalvular atrial fibrillation, Postoperative venous thrombophylaxis following hip or knee replacement surgery. **DOSAGE AND ADMINISTRATION:** 5 mg taken orally twice daily. **HEPATIC IMPAIRMENT:**No dose adjustment is required in patients with mild hepatic impairment. **RENAL IMPAIRMENT:** 2.5 mg twice daily in patients with any 2 of the following characteristics: age 80 years body weight 60 kg serum creatinine 1.5 mg/dL, then reduce dose to 2.5 mg twice daily. **CONTRAINDICATIONS:** Active pathological bleeding, Severe hypersensitivity reaction to **Apiraban®. WARNINGS AND PRECAUTIONS:** Discontinuing **Apiraban®** in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from **Apiraban®** to warfarin in clinical trials in patients with nonvalvular atrial fibrillation. If **Apiraban®** must be discontinued for a reason other than pathological bleeding, consider coverage with another anticoagulant. **Apiraban®** increases the risk of bleeding and can cause serious, potentially fatal, bleeding. Concomitant use of drugs affecting hemostasis increases the risk of bleeding. These include aspirin and other antiplatelet agents, other anticoagulants, heparin, thrombolytic agents, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitor, and nonsteroidal anti-inflammatory drugs (NSAIDs). The safety and efficacy of Apixaban has not been studied in patients with prosthetic heart valves. Therefore, use of Apixaban is not recommended in these patients. **ADVERSE REACTIONS:** Increased gamma-glutamyl transferase, gingival hemorrhage, nausea, , hematuria, hypermenorrhea, anemia, bruise, hematoma, rectal hemorrhage, postprocedural hemorrhage, increased serum transaminases, epistaxis, hemoptysis. **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. The dose of **Apiraban®**should be decreased to 2.5 mg twice daily when it is coadministered with drugs that are strong dual inhibitors of CYP3A4 and P-gp, (e.g., ketoconazole, itraconazole, ritonavir, or clarithromycin). Avoid concomitant use of **Apiraban®** with strong dual inducers of CYP3A4 and P-gp (e.g., rifampin, carbamazepine, phenytoin, St. John's wort) because such drugs will decrease exposure to apixaban. Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding. **PREGNANCY:** Pregnancy Category B. **LACTATION:** It is unknown whether apixaban or its metabolites are excreted in human milk. Rats excrete apixaban in milk (12% of the maternal dose). Women should be instructed either to discontinue breastfeeding or to discontinue **Apiraban®** therapy, taking into account the importance of the drug to the mother.

Advantages:

- ✓ Better safety profile
- ✓ Lower risk of major and gastrointestinal bleeding
- ✓ Favored in patients with Chronic Kidney Disease
- ✓ Lower rate of total discontinuation

Reference:

1. Lexicomp Drug Information Handbook 26th Edition, page 162-165
2. FDA Lable of Eliquis
3. Systemic review and meta-analysis of the efficacy and safety of apixaban compared to rivaroxaban in acute VTE in the real world, American society of Hematology, 2019