For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Apixaban™ Tablets 2.5mg / 5mg

SANOXABAN 2.5mg / 5mg

Composition: Each film-coated tablet contains Apixaban 2.5 mg / 5mg.
Indications : Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery; prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), including those with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); age ≥75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class ≥II) ; treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of recurrent DVT and PE in adult patients.

Posology and Method of Administration: *Prevention of VTE (VTEp)*: elective hip or knee replacement surgery – Recommended dose of apixaban is 2.5 mg taken orally twice daily. The initial dose should be taken 12 to 24 hours after surgery. In patients undergoing hip replacement surgery, the recommended duration of treatment is 32 to 38 days. In patients undergoing knee replacement surgery, the recommended duration of treatment is 10 to 14 days. *Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF):* The recommended dose of apixaban is 5 mg taken orally twice daily. *Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt) :* The recommended dose of apixaban for the treatment of acute DVT and treatment of PE is 10 mg taken orally twice daily for the first 7 days, followed by 5 mg taken orally twice daily. Duration of treatment is at least 3 months. The recommended dose of apixaban for the prevention of recurrent DVT and PE is 2.5 mg taken orally twice daily. In case of renal impairment dose adjustment is needed.

Contraindications : Hypersensitivity to the active substance or to any of the excipients; active clinically significant bleeding; hepatic disease associated with coagulopathy and clinically relevant bleeding risk; lesion or condition if considered a significant risk factor for major bleeding; concomitant treatment with any other anticoagulant agent except under specific circumstances of switching anticoagulant therapy, when UFH is given at doses necessary to maintain an open central venous or arterial catheter or when UFH is given during catheter ablation for atrial fibrillation.

Special warnings and precautions for use: Increased risk of thrombotic events after premature discontinuation. Apixaban increases the risk of bleeding and can cause serious, potentially fatal, bleeding. Concomitant use of drugs affecting hemostasis increases the risk of bleeding. Advise patients of signs and symptoms of blood loss and to report them immediately or go to an emergency room. Discontinue apixaban in patients with active pathological hemorrhage. The pharmacodynamic effect of apixaban can be expected to persist for at least 24 hours after the last dose. Prothrombin complex concentrate (PCC), activated prothrombin complex concentrate or recombinant factor VIIa may be considered for reversal of anticoagulant effect, but have not been evaluated in clinical studies. 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. Monitor patients frequently for signs and symptoms of neurological impairment. The safety and efficacy of apixaban have not been studied in patients with prosthetic heart valves, therefore not recommended. Initiation of apixaban is not recommended as an alternative to unfractionated heparin for the initial treatment of patients with PE who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy. Direct-acting oral anticoagulants (DOACs), including apixaban, are not recommended for use in patients with triple-positive antiphospholipid syndrome (APS). Apixaban has not been studied in patients undergoing hip fracture surgery, therefore it is not recommended. Clotting tests are affected by apixaban. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pregnancy: As a precautionary measure, it is preferable to avoid the use of apixaban during pregnancy.

Breast-feeding: A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from apixaban therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Undesirable effects: Common adverse reactions were haemorrhage, contusion, epistaxis, and haematoma.

For full prescribing information please write to: Sanofi India Ltd., Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Reference: Prescribing information of Apixaben Tablets (Eliquis®) dated June 2022.

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