ELIQUIS® (apixaban) 2.5 mg & 5 mg Film-coated Tablets

**Prescribing Information**

**PRECAUTIONS:** Indication: Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors (NVAF): Prevention of stroke and systemic embolism in adult patients with NVAF and one or more risk factors (NVAF: ≥ 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). Prevention of VTE in adult patients who have undergone elective hip or knee replacement surgery (VTE): Common: anaemia, haemorrhage, haematoma, nausea, confusion. Uncommon: thrombocytopenia; Hypotension (including procedural hypotension); specific haemorrhage such as respiratory tract, retroperitoneal.

**DRUG INTERACTIONS:** Increased risk of occult or overt bleeding from any tissue or organ, which may result in post haemorrhagic anaemia, signs, symptoms, and severity will vary according to the location and degree of the bleeding. PREGNANCY AND LACTATION: Pregnancy: Not recommended. Breastfeeding: Discontinue breastfeeding or discontinue Eliquis therapy. UNDESIRABLE EFFECTS: Increased risk of occult or overt bleeding from any tissue or organ, which may result in post haemorrhagic anaemia, signs, symptoms, and severity will vary according to the location and degree of the bleeding.

**ADVERSE REACTIONS:** Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (UK).

**CONTRAINDICATIONS:** Hypersensitivity to active substance or to 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 (refer to SmPC). Concomitant treatment with any other anticoagulant agent except under specific circumstances of switching anticoagulant therapy or when unfractionated heparin is given at doses necessary to maintain an open central venous or arterial catheter (refer to SmPC).

**WARNINGS AND PRECAUTIONS:** Haemorrhage: Monitoring of signs or symptoms for signs of bleeding is recommended. In patients treated with apixaban, antplatelet agents increases the risk of bleeding. Care with concomitant SSRIs, SNRIs or NSAIDs, including aspirin and dipyridamole. Eliquis should be used with caution when co-administered with any other anticoagulants is contraindicated. Due to an increased bleeding risk. Due to an increased bleeding risk. Eliquis exposure (e.g. severe renal impairment) (refer to SmPC).

**CLINICAL STUDIES:** In clinical trials conducted in patients undergoing hip fracture surgery, patients treated with Eliquis 5 mg twice daily had a lower rate of major bleeding events compared to patients treated with enoxaparin 30 mg twice daily. Post-procedural bleeding was reduced. The use of anticoagulants is contraindicated in patients with a past history of heparin-induced thrombocytopenia and a positive heparin-induced thrombocytopenia (HIT) test result. In patients with active cancer: Eliquis is not recommended.

**PHARMACOKINETICS:** Eliquis is not recommended as an alternative to unfractionated heparin in patients with pulmonary embolism who are haemodynamically unstable or may receive inoperable or mildly operable pulmonary embolism. Eliquis is not recommended as an alternative to unfractionated heparin in patients with pulmonary embolism who are haemodynamically unstable or may receive inoperable or mildly operable pulmonary embolism. Eliquis should be used with caution when co-administered with any other anticoagulants is contraindicated. Due to an increased bleeding risk. Due to an increased bleeding risk. Eliquis exposure (e.g. severe renal impairment) (refer to SmPC).

**EFFECT ON LABORATORY TESTS:** Eliquis should be used with caution when co-administered with any other anticoagulants is contraindicated. Due to an increased bleeding risk. Due to an increased bleeding risk. Eliquis exposure (e.g. severe renal impairment) (refer to SmPC).

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