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

Prescribing Information

Consult Summary of Product Characteristics (SmPC) before prescribing.

PRESENTATION: Film-coated tablets; 5 mg and 2.5 mg apixaban.

INDICATION: Prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA), age ≥ 75 years, hypertension, diabetes mellitus, chronic obstructive pulmonary disease (COPD) or symptomatic peripheral arterial disease (PAD). Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in patients (see Special warnings and precautions for information on haemorrhagic complications). Treatment of venous thromboembolic events (VTE) in adults who have undergone elective hip or knee replacement surgery (2.5 mg only).

DOSE AND ADMINISTRATION: Oral. Taken with water, with or without food.

Treating stroke and systemic embolism in patients with NVAF: The recommended dose is 5 mg twice a day. In patients who meet at least two of the following criteria: serum creatinine ≥ 1.5 mg/dL (133 micromole/L), age ≥ 80 years, or body weight ≤ 60 kg, the recommended dose is 2.5 mg twice daily. In patients with severe renal impairment (creatinine clearance 15-29 mL/min) should receive Eliquis 2.5 mg twice daily. Therapy should be continued long term. Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE): The recommended dose for the treatment of acute DVT and treatment of PE is 10 mg twice daily for the first 7 days followed by 5 mg twice daily. As per available medical guidelines, short duration of treatment (at least 3 months) should be based on the risk of thrombotic or bleeding risk factors (e.g. recent surgery, trauma patients). The recommended dose for the prevention of recurrent DVT and PE is 2.5 mg twice daily.

When prevention of recurrent DVT and PE is indicated, the 2.5 mg twice daily dose should be initiated following completion of 6 months of treatment with Eliquis 5 mg twice daily or with another anticoagulant. The duration of overall treatment should be individualised after careful assessment of the treatment benefit against the potential risks should be made before combining with other anticoagulants, including Eliquis, for active cancer, elective surgery, or invasive procedures.

Switching treatment from Eliquis to other anticoagulants increases the risk of bleeding. Care with switching treatment from Eliquis to other anticoagulants is recommended dose for the treatment of acute ischemic stroke; Limited experience.

Patients with atrial fibrillation (AF) have been studied in patients with or without transcatheter atrial fibrillation. Therefore, the use of Eliquis is not recommended in this setting.

Patients with antiphospholipid syndrome: Direct acting Oral Anticoagulants (DOACs), including Eliquis, are not recommended for patients with a history of thrombosis who are receiving aspirin (see SmPC for further details).

Surgery and invasive procedures: Discontinue at least 48 hours prior to elective surgery or invasive procedures with a moderate or high risk of bleeding. Discontinue Eliquis 24 hours prior to or during surgery or invasive procedures with a low risk of bleeding. If surgery or invasive procedures cannot be delayed, appropriate caution should be exercised, taking into consideration an increased risk of bleeding. Eliquis should be restarted after the invasive procedure as long as the clinical situation allows and adequate haemostasis has been established. For patients undergoing catheter ablation for atrial fibrillation, Eliquis treatment does not need to be interrupted. In patients requiring catheter ablation and receiving anticoagulants, including Eliquis, for active cancer, elective surgery, or invasive procedures, Eliquis should be temporarily discontinued for any reason, therapy should be restarted as soon as possible.

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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 (VTEp):

**Common**: anaemia; haemorrhage*; haematoma*; nausea; contusion.

**Uncommon**: thrombocytopenia*; epistaxis*; haematochezia*; liver function test abnormal (including blood bilirubin increased*); haematuria*; specific haemorrhage such as gastrointestinal*; abnormal vaginal*; urogenital*; post procedural*; wound secretion*; incision site*; operative*.

**Rare**: hypersensitivity*; anaphylaxis*; haemoptysis*; gingival bleeding*; specific haemorrhage such as eye (including conjunctival)*; rectal*; muscle*.

**Not known**: angioedema*; specific haemorrhage such as brain (encompassing intracranial; intraspinal)*, intra-abdominal*, respiratory tract*, haemorrhoidal*; mouth*; retroperitoneal*; traumatic*.

Prevention of stroke and systemic embolism in adult patients with NVAF, with one or more risk factors (NVAF):

**Common**: anaemia; haemorrhage*; haematoma*; hypotension (including procedural hypotension); epistaxis*; nausea; gingival bleeding*; gamma-glutamyltransferase increased; haematuria*; contusion; specific haemorrhage such as eye (including conjunctival)*, gastrointestinal*; rectal*.

**Uncommon**: thrombocytopenia*; hypersensitivity*; anaphylaxis*; haemoptysis*; haematochezia*; liver function test abnormal (including blood bilirubin increased*); specific haemorrhage such as brain (encompassing intracranial, intraspinal)*, intra-abdominal*, mouth*; abnormal vaginal*; urogenital*; post procedural*; wound secretion*; incision site*; operative*; traumatic*.

**Rare**: specific haemorrhage such as eye (including conjunctival)*, haemorrhoidia*; muscle*; hypersensitivity*; anaphylaxis*; haemoptysis*; haematochezia*; liver function test abnormal (including blood bilirubin increased*); specific haemorrhage such as eye (including conjunctival)*, haemorrhoidia*; muscle*; post procedural*; wound secretion*; incision site*; operative*; traumatic*.

**Not known**: angioedema*; specific haemorrhage such as brain (encompassing intracranial, intraspinal)*, respiratory tract*.

*Denotes serious adverse reaction

Refer to SmPC for all other adverse events

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER: EU/1/11/691/002-3, EU/1/11/691/008, EU/1/11/691/014

PACKAGE QUANTITIES: Carton of 20 film-coated tablets 2.5 mg, 60 film-coated tablets 2.5 mg, 28 film-coated tablets 5 mg.

MARKETING AUTHORISATION HOLDER: Bristol-Myers Squibb/Pfizer EEIG

LOCAL REPRESENTATIVE IN IRELAND: Bristol-Myers Squibb Pharmaceuticals uc, Plaza 254, Blanchardstown Corporate Park 2, Dublin 15, D15 TB67, Ireland. Tel: 01 483 3625

DATE OF LAST REVISION: August 2020

ADDITIONAL INFORMATION AVAILABLE ON REQUEST

Mercury Internal Ref. no: 432IE2005806-01

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**Adverse events should be reported. Reporting forms and information can be found at:**

Ireland - via HPRA Pharmacovigilance at www.hpra.ie

Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 1 800 749 749 (Ireland)