פייזר פרמצבטיקה ישראל בע"מ
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מרץ 2025

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא (בלבד) של **Eliquis 2.5mg, Eliquis 5mg :**

**APIXABAN 2.5mg Indicated for:**
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), with One or more risk factors, such as prior stroke or transient ischaemic 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 adults.

**APIXABAN 5mg Indicated for:**
Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more risk factors, such as prior stroke or transient ischaemic attack (TIA); age ≥75 hypertension; diabetes mellitus, symptomatic heart failure (NYHA Class ≥ II).
Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults

**להלן העדכונים העיקריים בעלון לרופא:**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 2.5 mg film-coated tablet contains 51~~.4~~ mg lactose.
Each 5 mg film-coated tablet contains ~~102.9~~ 103 mg lactose (see section 4.4).

**3. PHARMACEUTICAL FORM**

Film-coated tablet

Eliquis 2.5 mg - yellow, round tablets (diameter of ~~5.95~~ 6 mm) debossed with 893 on one side and 2½ on the other side.

Eliquis 5 mg - pink, oval tablets (~~9.73~~ 10 mm x ~~5.16~~ 5 mm) debossed with 894 on one side and 5 on the other side.

**4.3 Contraindications**

- Concomitant treatment with any other anticoagulant agent e.g. unfractionated heparin (UFH), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, rivaroxaban, dabigatran, etexilate etc.) except under specific circumstances of switching anticoagulant therapy (see section 4.2) or when UFH is given at doses necessary to maintain an open central venous or arterial catheter (see section 4.5).

**4.4 Special warnings and precautions for use**

- A specific reversal agent (andexanet alfa) antagonising the pharmacodynamic effect of apixaban is available for adults. (refer to the summary of product characteristics of andexanet alfa). Transfusion of fresh frozen plasma, administration of prothrombin complex concentrates (PCCs), or recombinant factor VIIa may be considered. However, there is no clinical experience with the use of 4-factor PCC products to reverse bleeding in paediatric and adult patients who have received apixaban.

**4.9 Overdose**

~~There is no antidote to apixaban.~~ Overdose of apixaban may result in a higher risk of bleeding. In the event of haemorrhagic complications, treatment must be discontinued and the source of bleeding investigated. The initiation of appropriate treatment, e.g., surgical haemostasis or the transfusion of fresh frozen plasma or the administration of a reversal agent for factor Xa inhibitors should be considered (see section 4.4).

Haemodialysis decreased apixaban AUC by 14% in subjects with end-stage renal disease (ESRD), when a single dose of apixaban 5 mg was administered orally. Therefore, haemodialysis is unlikely to be an effective means of managing apixaban overdose.

For situations in which reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding ~~cannot be controlled by the above measures, administration~~ a reversal agent for factor Xa inhibitors (andexanet alfa) is available for adults (see section 4.4). Administration of prothrombin complex concentrates (PCCs) or recombinant factor VIIa may also be considered. Reversal of apixaban pharmacodynamic effects, as demonstrated by changes in the thrombin generation assay, was evident at the end of infusion and reached baseline values within 4 hours after the start of a 30 minute 4-factor PCC ~~30 minute~~ infusion in healthy subjects. However, there is no clinical experience with the use of 4-factor PCC products to reverse bleeding in individuals who have received apixaban. Currently there is no experience with the use of recombinant factor VIIa in individuals receiving apixaban. Re-dosing of recombinant factor VIIa could be considered and titrated depending on improvement of bleeding.

Depending on local availability, ~~a consultation~~ a coagulation expert consultation should be considered in case of major bleeding.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
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