



דצמבר 2024

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רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא 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 \geq 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 \geq II).
Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults

להלן העדכונים העיקריים בעלון לרופא:

4.2 Posology and method of administration

Patients undergoing cardioversion

Apixaban can be initiated or continued in NVAf patients who may require cardioversion.

For patients not previously treated with anticoagulants, exclusion of left atrial thrombus using an image guided approach (e.g. transesophageal echocardiography (TEE) or computed tomographic scan (CT)) prior to cardioversion should be considered, in accordance with established medical guidelines.

For patients initiating treatment with apixaban, 5 mg should be given twice daily for at least 2.5 days (5 single doses) before cardioversion to ensure adequate anticoagulation (see section 5.1). The dosing regimen should be reduced to 2.5 mg apixaban given twice daily for at least 2.5 days (5 single doses) if the patient meets the criteria for dose reduction (see above sections *Dose reduction* and *Renal impairment*).

If cardioversion is required before 5 doses of apixaban can be administered, a 10 mg loading dose should be given, followed by 5 mg twice daily. The dosing regimen should be reduced to a 5 mg loading dose followed by 2.5 mg twice daily if the patient meets the criteria for dose reduction (see above sections *Dose reduction* and *Renal impairment*). The administration of the loading dose should be given at least 2 hours before cardioversion (see section 5.1).

For all patients undergoing cardioversion, confirmation should be sought prior to cardioversion that the patient has taken apixaban as prescribed. Decisions on initiation and duration of treatment should take established guideline recommendations for anticoagulant treatment in patients undergoing cardioversion into account.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Patients undergoing cardioversion

EMANATE, an open-label, multi-center study, enrolled 1500 patients who were either oral anticoagulant naïve or pre-treated less than 48 hours, and scheduled for cardioversion for NVAf. Patients were randomized 1:1 to apixaban or to heparin and/or VKA for the prevention of cardiovascular events. Electrical and/or pharmacologic cardioversion was conducted after at least 5 doses of 5 mg twice daily apixaban (or 2.5 mg twice daily in selected patients (see section 4.2)) or at least 2 hours after a 10 mg loading dose (or a 5 mg loading dose in selected patients (see section 4.2)) if earlier cardioversion was required. In the

apixaban group, 342 patients received a loading dose (331 patients received the 10 mg dose and 11 patients received the 5 mg dose).

There were no strokes (0%) in the apixaban group (n= 753) and 6 (0.80%) strokes in the heparin and/or VKA group (n = 747; RR 0.00, 95% CI 0.00, 0.64). All-cause death occurred in 2 patients (0.27%) in the apixaban group and 1 patient (0.13%) in the heparin and/or VKA group. No systemic embolism events were reported.

Major bleeding and CRNM bleeding events occurred in 3 (0.41%) and 11 (1.50%) patients, respectively, in the apixaban group, compared to 6 (0.83%) and 13 (1.80%) patients in the heparin and/or VKA group.

This exploratory study showed comparable efficacy and safety between apixaban and heparin and/or VKA treatment groups in the setting of cardioversion.

להלן העדכונים העיקריים בעלון לצרכן:

3. כיצד תשתמש בתרופה?

מטופלים אשר עוברים היפוך חשמלי

במידה ויש להחזיר את פעימות הלב הלא סדירות שלך למצב סדיר על ידי הליך רפואי הנקרא היפוך חשמלי (Cardioversion), קח את אליקוויס בזמנים בהם הרופא שלך מנחה אותך, בכדי למנוע קרישי דם בכלי הדם במוח ובכלי דם אחרים בגופך.

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,
אורטל עבודי
רוקחת ממונה