



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2012
EMA/CHMP/608476/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Eliquis apixaban

On 20 September 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Eliquis. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb / Pfizer EEIG. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication for the existing 2.5 mg strength and a new 5 mg strength as follows:

“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 \geq 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class \geq II).”

The CHMP adopted two new contraindications as follows:

- “Lesion or condition at significant risk of major bleeding such as current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.
- Concomitant treatment with any other anticoagulant agent e.g. unfractionated heparin (UHF), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, rivaroxaban, dabigatran, etc.) except under the circumstances of switching therapy to or from apixaban (see section 4.2) or when UHF is given at doses necessary to maintain a patent central venous or arterial catheter”

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.



The CHMP adopted a change to a contraindication as follows:

"Hypersensitivity to the active substance or to any of the excipients **listed in section 6.1.**"

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Eliquis will be as follows²:

Eliquis 2.5 mg film-coated tablets:

"Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery.

Eliquis 2.5 mg and 5 mg film-coated tablets:

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 \geq 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class \geq II)."

For information, the full contraindications for Eliquis will be as follows³:

- "Hypersensitivity to the active substance or to any of the excipients **listed in section 6.1.**
- Clinically significant active bleeding.
- Hepatic disease associated with coagulopathy and clinically relevant bleeding risk (see section 5.2).
- **Lesion or condition at significant risk of major bleeding such as current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.**
- **Concomitant treatment with any other anticoagulant agent e.g. unfractionated heparin (UHF), low molecular weight heparins (enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, rivaroxaban, dabigatran, etc.) except under the circumstances of switching therapy to or from apixaban (see section 4.2) or when UHF is given at doses necessary to maintain a patent central venous or arterial catheter."**

² The text in bold represents the new or the amended indication.

³ The text in bold represents the new or the amended contraindication.