30 May 2024
EMA/CHMP/247780/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Eliquis

apixaban

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change 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.

The CHMP adopted an extension to the existing indication to include treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in children, associated with the addition of new pharmaceutical forms and new strengths (0.15 mg granules in capsules for opening, as well as 0.5, 1.5 and 2 mg coated granules in sachet).

For information, the full indication is:[2]

Adults

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 (see section 4.4 for haemodynamically unstable PE patients).

Paediatric population

Treatment of venous thromboembolism (VTE) and prevention of recurrent VTE in paediatric patients from 28 days to less than 18 years of age.

Detailed recommendations 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 made available in all official European Union languages after a decision on this change to the

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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marketing authorisation has been granted by the European Commission.