28 May 2020
EMA/270403/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Apixaban Accord

apixaban

On 28 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apixaban Accord, intended for the treatment and prevention of venous thromboembolic events (VTE) in adult patients and for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF). The applicant for this medicinal product is Accord Healthcare S.L.U.

Apixaban Accord will be available as 2.5 mg and 5 mg film-coated tablets. The active substance of Apixaban Accord is apixaban, an anticoagulant, (ATC code: B01AF02) which acts as a direct and highly selective inhibitor of factor Xa.

Apixaban Accord is a generic of Eliquis, which has been authorised in the EU since 18 May 2011. Studies have demonstrated the satisfactory quality of Apixaban Accord, and its bioequivalence to the reference product Eliquis. A question and answer document on generic medicines can be found here.

The full indication is:

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

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

[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

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