17 September 2020
EMA/CHMP/484813/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rivaroxaban Accord

rivaroxaban

On 17 September 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 Rivaroxaban Accord, an anticoagulant intended for the treatment and prevention of venous thromboembolism, pulmonary embolism, and the prevention of atherothrombotic events in adults with various risk factors for such events.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Rivaroxaban Accord will be available as 2.5-mg, 10-mg, 15-mg and 20-mg film-coated tablets. The active substance of Rivaroxaban Accord is rivaroxaban, an antithrombotic agent (ATC code: B01AF01) which acts as a direct factor Xa inhibitor.

Rivaroxaban Accord is a generic of Xarelto, which has been authorised in the EU since 30 September 2008. Studies have demonstrated the satisfactory quality of Rivaroxaban Accord and its bioequivalence to the reference product Xarelto. A question and answer document on generic medicines can be found here.

The full indication is:

> Rivaroxaban Accord, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers (see sections 4.3, 4.4 and 5.1) (2.5 mg)
>
> Co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events (2.5 mg).
>
> Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery (10 mg).

[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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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) (10, 15 and 20 mg).

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (15 and 20 mg).

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.