16 September 2021
EMA/CHMP/513776/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rivaroxaban Mylan

Rivaroxaban

On 16 September 2021, 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 Mylan, intended for the prevention of venous thromboembolism, the treatment and prevention of deep vein thrombosis and pulmonary embolism, and the prevention of atherothrombotic events, stroke and systemic embolism in adults with various risk factors for such events, as well as the treatment and prevention of venous thromboembolism in children and adolescents.

The applicant for this medicinal product is Mylan Ireland Limited.

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

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

The full indication is:

> Rivaroxaban Mylan, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or 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)
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> Rivaroxaban Mylan, 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).
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> 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 mg, 15 mg, 20 mg and 15+20 mg initiation pack).

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 mg and 20 mg).

Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment (15 mg).

Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment (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.