18 September 2025
EMA/CHMP/297836/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rivaroxaban Koanaa

rivaroxaban

On 18 September 2025, 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 Koanaa, intended for the prevention of venous thromboembolism, the treatment and prevention of deep vein thrombosis and pulmonary embolism, and the prevention of 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 Koanaa Healthcare Spain, S.L.

Rivaroxaban Koanaa will be available as 10 mg, 15 mg and 20 mg orodispersible films. The active substance of Rivaroxaban Koanaa is rivaroxaban, an antithrombotic agent (ATC code: B01AF01). Rivaroxaban is a highly selective, direct factor Xa inhibitor. Inhibition of factor Xa interrupts the intrinsic and extrinsic pathways of the blood coagulation cascade, inhibiting both thrombin formation and the development of thrombi.

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

The full indications for Rivaroxaban Koanaa 10 mg orodispersible films will be as follows:

> Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.
>
> 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).

[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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The full indications for Rivaroxaban Koanaa 15 mg orodispersible films will be as follows:

Adults

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.

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 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.

The full indications for Rivaroxaban Koanaa 20 mg orodispersible films will be as follows:

Adults

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.

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 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.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.