14 December 2023
EMA/CHMP/556286/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dabigatran Etexilate Leon Farma

dabigatran etexilate

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dabigatran Etexilate Leon Farma, intended for primary prevention and treatment of venous thromboembolic events and prevention of recurrent episodes, prevention of stroke and systemic embolism, and treatment of deep vein thrombosis and pulmonary embolism and prevention of recurrent episodes.

The applicant for this medicinal product is Laboratorios Leon Farma S.A.

Dabigatran Etexilate Leon Farma will be available as 75 mg, 110 mg and 150 mg hard capsules. The active substance of Dabigatran Etexilate Leon Farma is dabigatran etexilate, an antithrombotic agent (ATC code: B01AE07). Dabigatran etexilate is a prodrug that is metabolised to dabigatran, a direct thrombin inhibitor. Since thrombin enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of blood clots.

Dabigatran Etexilate Leon Farma is a generic of Pradaxa, which has been authorised in the EU since 18 March 2008. Studies have demonstrated the satisfactory quality of Dabigatran Etexilate Leon Farma, and its bioequivalence to the reference product Pradaxa. A question and answer document on generic medicines can be found here.

The full indication is:

> Dabigatran etexilate Leon Farma 75 mg hard capsule
>
> Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.
>
> Treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age.
>
> For age appropriate dose forms, see section 4.2.

[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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Dabigatran etexilate Leon Farma 110 mg hard capsule

Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective total hip replacement surgery or total 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 ischemic attack (TIA); age ≥ 75 years; heart failure (NYHA Class ≥ II); diabetes mellitus; hypertension.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Treatment of VTE and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age.

For age appropriate dose forms, see section 4.2.

Dabigatran etexilate Leon Farma 150 mg hard capsule

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 ischemic attack (TIA); age ≥ 75 years; heart failure (NYHA Class ≥ II); diabetes mellitus; hypertension.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Treatment of venous thromboembolic events (VTE) and prevention of recurrent VTE in paediatric patients from birth to less than 18 years of age.

For age appropriate dose forms, see section 4.2.

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.