12 November 2020
EMA/CHMP/585170/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pradaxa

dabigatran etexilate

On 12 November 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Pradaxa. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new pharmaceutical form and strength – coated granules (20 mg, 30 mg, 40 mg, 50 mg, 110 mg, 150 mg) and powder and solvent for oral solution (6.25 mg/ml) – together with a new indication as follows: [2]

> **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.**

The CHMP also adopted this indication for the 75 mg, 110mg and 150 mg strength of the already authorised hard capsules form as follows:[2]

Pradaxa 75 mg:

> 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.**

Pradaxa 110 mg:

> Primary prevention of venous thromboembolic events (VTE) in adult patients who have undergone

[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
[2] New text in **bold,** , removed text as ~~strikethrough~~

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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.

Pradaxa 150 mg:

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

The CHMP also adopted the new contraindication for all the above strengths of hard capsules as follows:

- ~~Patients with s~~Severe renal impairment (CrCL <30 mL/min) **in adult patients**
- **eGFR <50 mL/min/1.73m^2 in paediatric patients**

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