



9 November 2023
EMA/CHMP/498446/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Pradaxa

dabigatran etexilate

On 9 November 2023, 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 the removal of a pharmaceutical form (powder and solvent for oral solution) and a change to an existing indication for the use of Pradaxa in children under 18 years of age. For information, the full indications for Pradaxa will be as follows:²

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 \geq 75 years; heart failure (NYHA Class \geq 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~~ the time the child is able to swallow soft food 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 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.

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

