21 November 2013
EMA/CHMP/719108/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pradaxa

dabigatran etexilate

On 21 November 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation 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. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

"Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), with one or more ~~**of the following**~~ risk factors, **such as**

- ~~**Previous**~~ prior stroke or, transient ischemic attack (TIA); ~~**or systemic embolism (SEE);**~~
- ~~**Left ventricular ejection fraction < 40 %**~~
- ~~**Symptomatic**~~ heart failure (~~**≥ New York Heart Association (**~~NYHA ~~**)**~~ Class ≥ II~~**≥ 2**~~);
- Age ≥ 75 years
- ~~**Age ≥ 65 years associated with one of the following:**~~ diabetes mellitus; ~~**coronary artery disease;, or**~~ hypertension."

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Pradaxa will be as follows[2]:

<u>75 mg strength</u>

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended indication.

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“Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.”

110 mg strength

“Primary prevention of venous thromboembolic events 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.”

150 mg strength

“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.”