17 December 2015
EMA/CHMP/730883/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion1 (post authorisation)

Brilique

ticagrelor

On 17 December 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Brilique. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new indication and a change to the existing indication as follows[2]:

"Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with

- acute coronary syndromes (ACS) ~~(unstable angina, non ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG)~~ **or**
- **a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event (see sections 4.2 and 5.1)."**

As the recommended dose for patients with a history of MI is 60 mg twice daily, the CHMP also recommended extending the marketing authorisation to include 60 mg film-coated tablets.

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

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