EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/CHMP/420912/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zontivity

Vorapaxar

On 23 June 2016, 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 Zontivity. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme Limited.

The CHMP adopted an extension to the existing indication as follows[2]:

"Zontivity~~, co-administered with acetyl salicylic acid (ASA) and, where appropriate, clopidogrel~~, is indicated for the reduction of atherothrombotic events in adult patients with

- a history of myocardial infarction (MI), **co-administered with acetylsalicylic acid (ASA) and, where appropriate, clopidogrel; or**
- **symptomatic peripheral arterial disease (PAD), co-administered with acetylsalicylic acid (ASA) or, where appropriate, clopidogrel.**"

For information, the full indication(s) for Zontivity will be as follows:

Zontivity is indicated for the reduction of atherothrombotic events in adult patients with

a history of myocardial infarction (MI), co-administered with acetylsalicylic acid (ASA) and, where appropriate, clopidogrel; or
symptomatic peripheral arterial disease (PAD), co-administered with acetylsalicylic acid (ASA) or, where appropriate, clopidogrel.

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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