10 November 2022
EMA/862229/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

DuoPlavin

clopidogrel / acetylsalicylic acid

On 10 November 2022, 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 DuoPlavin. The marketing authorisation holder for this medicinal product is sanofi-aventis groupe.

The CHMP adopted a change to the existing indication to include the secondary prevention of atherothrombotic events in patients with ST segment elevation acute myocardial infarction (STEMI) undergoing percutaneous coronary intervention (PCI):

"

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

> DuoPlavin is indicated for the secondary prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). DuoPlavin is a fixed-dose combination medicinal product for continuation of therapy in:
>
> - Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction) including patients undergoing a stent placement following percutaneous coronary intervention **(PCI)**
> - ST segment elevation acute myocardial infarction **(STEMI) in patients undergoing PCI (including patients undergoing a stent placement) or** medically treated patients eligible for thrombolytic**/ fibrinolytic** therapy
>
> For further information please refer to section 5.1.

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

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