14 November 2019
EMA/419889/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Clopidogrel/Acetylsalicylic acid Mylan

clopidogrel / acetylsalicylic acid

On 14 November 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Clopidogrel/Acetylsalicylic acid Mylan, intended for the secondary prevention of atherothrombotic events. The applicant for this medicinal product is Mylan S.A.S.

Clopidogrel/Acetylsalicylic acid Mylan will be available as film-coated tablets (75 mg clopidogrel with 75 or 100 mg acetylsalicylic acid). The active substances, clopidogrel and acetylsalicylic acid, are antithrombotic agents (ATC code: B01AC30). The active metabolite of clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet $P2Y_{12}$ receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Acetylsalicylic acid also inhibits platelet aggregation by irreversible inhibition of prostaglandin cyclo-oxygenase and thus inhibits the generation of thromboxane A_2, an inducer of platelet aggregation and vasoconstriction.

Clopidogrel/Acetylsalicylic acid Mylan is a generic of DuoPlavin, which has been authorised in the EU since 15 March 2010. Studies have demonstrated the satisfactory quality of Clopidogrel/Acetylsalicylic acid Mylan, and its bioequivalence to the reference product DuoPlavin. A question and answer document on generic medicines can be found here.

The full indication is:

“Clopidogrel/Acetylsalicylic acid Mylan is indicated for the secondary prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). Clopidogrel/Acetylsalicylic acid Mylan 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
- ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy“

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.