22 March 2018
EMA/CHMP/50933/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Prasugrel Mylan

prasugrel

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Prasugrel Mylan, intended to be given with acetylsalicylic acid for the prevention of atherothrombotic events in adults with acute coronary syndromes who are undergoing percutaneous coronary intervention.

The applicant for this medicinal product is Mylan S.A.S.

Prasugrel Mylan will be available as 5- and 10-mg film-coated tablets. The active substance of Prasugrel Mylan is prasugrel, an inhibitor of platelet activation and aggregation (ATC code: B01AC22). Prasugrel acts through the irreversible binding of its active metabolite to the P2Y12 class of ADP receptors on platelets. Since platelets participate in the initiation and/or evolution of thrombotic complications of atherosclerotic disease, inhibition of platelet function can result in the reduction of the rate of cardiovascular events such as death, myocardial infarction, or stroke.

Prasugrel Mylan is a generic of Efient, which has been authorised in the EU since 23 February 2009. Studies have demonstrated the satisfactory quality of Prasugrel Mylan, and its bioequivalence to the reference product Efient. A question and answer document on generic medicines can be found here.

The full indication is:

> "Prasugrel Mylan, co administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).
>
> For further information please refer to section 5.1".

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

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

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