EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/CHMP/369651/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Clopidogrel/Acetylsalicylic acid Teva

clopidogrel / acetylsalicylic acid

On 26 June 2014, 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 Teva, (Clopidogrel 75mg- ASA 75mg, Clopidogrel 75mg- ASA 100mg film coated tablets intended for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substances of Clopidogrel/Acetylsalicylic acid Teva are Clopidogrel and acetylsalicylic acid , pharmacothepareutic classs/ATC code B01AC30 and are platelet aggregation inhibitiors.

The benefits with Clopidogrel/Acetylsalicylic acid Teva are its ability to selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet P2Y12 receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation and prevent occurrence of atherothrombotic events. The most common side effects are bleeding, haematoma, epistaxis, gastrointestinal haemorrhage, diarrhoea, abdominal pain, dyspepsia, bruising, bleeding at the puncture site.

A pharmacovigilance plan for Clopidogrel/Acetylsalicylic acid Teva will be implemented as part of the marketing authorisation.

The approved indication is:

"Clopidogrel/Acetylsalicylic acid Teva is indicated for the prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). Clopidogrel/Acetylsalicylic acid Teva 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

[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.

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- ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy”

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Clopidogrel/Acetylsalicylic acid Teva and therefore recommends the granting of the marketing authorisation.