22 July 2010
EMA/CHMP/289096/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Clopidogrel Teva Pharma B.V.

clopidogrel hydrobromide

On 22 July 2010 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 Teva Pharma B.V 75 mg, film-coated tablet intended for use in adults for the prevention of atherothrombotic events in patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease, and in patients suffering from acute coronary syndrome. 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 substance of Clopidogrel Teva Pharma B.V. is clopidogrel (as hydrobromide), a platelet aggregation inhibitor other than heparin (ATC code: B01AC04). Clopidogrel selectively inhibits the binding of ADP to its platelet receptor, and the subsequent ADP-mediated activation of the GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Biotransformation of clopidogrel is necessary to produce inhibition of platelet aggregation.

The benefit with Clopidogrel Teva Pharma B.V. is its ability to reduce the relative risk of death, re-infarction or stroke when administered after recent myocardial infarction or recent stroke and in patients suffering from established arterial disease and acute coronary syndrome. The most common side effect is bleeding and bleeding-associated events (haematoma, epistaxis, gastrointestinal haemorrhage, bruising). Also abdominal pain and dyspepsia are quite common.

Clopidogrel Teva Pharma B.V. is a generic of Plavix, which has been authorised in the EU since 15 July 1998. Studies have demonstrated the satisfactory quality of Clopidogrel Teva Pharma B.V., and its bioequivalence with the reference product Plavix. A question and answer document on generic medicines can be found here.

[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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A pharmacovigilance plan for Clopidogrel Teva Pharma B.V. will be implemented as part of the marketing authorisation.

The approved indication is: “in adults for the prevention of atherothrombotic events in:

- Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.

- Patients suffering from acute coronary syndrome:
  - 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, in combination with acetylsalicylic acid (ASA)
  - ST segment elevation acute myocardial infarction, in combination with ASA in medially treated patients eligible for thrombolytic therapy”.

It is proposed that Clopidogrel Teva Pharma B.V. is prescribed by physicians experienced in the treatment of cardiovascular diseases.

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 will be 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 Teva Pharma B.V. and therefore recommends the granting of the marketing authorisation.