18 December 2014
EMA/CHMP/476872/2014
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Clopidogrel ratiopharm

clopidogrel

On 18 December 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 ratiopharm, 75 mg, film-coated tablet intended for prevention of atherothrombotic events in adult patients suffering from myocardial infarction, ischaemic stroke, established peripheral arterial disease or acute coronary syndrome and for prevention of atherothrombotic and thromboembolic events in adult patients with atrial fibrillation.

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 ratiopharm is clopidogrel (as clopidogrel hydrogen sulphate) a non-competitive inhibitor of platelet aggregation (ATC code B01AC04). Clopidogrel is a prodrug, it must be metabolised by CYP450 enzymes to produce the active metabolite that 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.

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

A pharmacovigilance plan for Clopidogrel ratiopharm will be implemented as part of the marketing authorisation.

The approved indication is:

Prevention of atherothrombotic events in:

[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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- Adult 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.
- Adult 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 medically treated patients eligible for thrombolytic therapy.

and

Prevention of atherothrombotic and thromboembolic events in atrial fibrillation in:

- Adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

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 Ratiopharm and therefore recommends the granting of the marketing authorisation.