European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
CLOPIDOGREL BMS

International Nonproprietary Name (INN): ***clopidogrel***

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Clopidogrel BMS, 75 mg and 300mg film-coated tablet intended for prophylaxis against atherothrombotic events in patients suffering from myocardial infarction, ischaemic stroke or established peripheral arterial disease; and patients suffering from acute coronary syndrome. The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The active substance of Clopidogrel BMS is clopidogrel, a platelet aggregation inhibitors excl. heparin medicinal product (B01AC04). Clopidogrel BMS 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.

The clinical benefit of Clopidogrel BMS is the reduction it produces in the incidence of new ischaemic events in patients with clinical evidence of atherosclerosis. The most common side effects are bleeding, diarrhoea, abdominal pain and dyspepsia.

A pharmacovigilance plan for Clopidogrel BMS, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:

Clopidogrel is indicated 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 medically treated patients eligible for thrombolytic therapy.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

*corr.: The International Nonproprietary Name has been corrected.

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Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) 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 of the reference product, considers that there is a favourable benefit-risk balance for Clopidogrel BMS and therefore recommends the granting of the marketing authorisation.