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Clopidogrel BMS
clopidogrel

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Clopidogrel BMS?
Clopidogrel BMS is a medicine that contains the active substance clopidogrel. It is available as pink tablets (round: 75 mg; oblong: 300 mg).

What is Clopidogrel BMS used for?
Clopidogrel BMS is used in adults to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries). Clopidogrel BMS can be given to the following groups of patients:
- patients who have recently had a myocardial infarction (heart attack). Clopidogrel BMS can be started between a few days and 35 days after the attack;
- patients who have had a recent ischaemic stroke (stroke caused by the failure of the blood supply to part of the brain). Clopidogrel BMS can be started between seven days and six months after the stroke;
- patients with peripheral arterial disease (problems with blood flow in the arteries);
- patients who have a condition known as 'acute coronary syndrome', when it should be given with aspirin (another medicine that prevents blood clots), including patients who have had a stent inserted (a short tube placed in an artery to prevent it closing up). Clopidogrel BMS can be used in patients who are having a heart attack with an 'ST segment elevation' (an abnormal reading on the ECG or electrocardiogram) when the doctor thinks that they would benefit from the treatment. It can also be used in patients who do not have this abnormal reading on the ECG, if they have unstable angina (a severe type of chest pain) or have had a 'non-Q-wave' myocardial infarction.

The medicine can only be obtained with a prescription.

How is Clopidogrel BMS used?
The standard dose of Clopidogrel BMS is one 75-mg tablet once a day, taken with or without food. In acute coronary syndrome, Clopidogrel BMS is used together with aspirin and treatment generally starts with a loading dose of one 300-mg tablet or four 75-mg tablets. This is then followed by the standard 75-mg dose once a day for at least four weeks (in ST segment elevation myocardial infarction) or for up to 12 months (in non-ST segment elevation syndrome).
Clopidogrel BMS is converted into its active form in the body. For genetic reasons, some patients may not be able to convert Clopidogrel BMS as effectively as others, which could reduce their response to the medicine. The best dose to use in these patients has not yet been determined.

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How does Clopidogrel BMS work?
The active substance in Clopidogrel BMS, clopidogrel, is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. When the blood clots, this is due to special cells in the blood called platelets aggregating (sticking together). Clopidogrel stops the platelets aggregating by blocking a substance called ADP from attaching to a special receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent another heart attack or stroke.

How has Clopidogrel BMS been studied?
Clopidogrel BMS has been compared with aspirin in a study called CAPRIE including around 19,000 patients who had recently had a heart attack or an ischaemic stroke, or who had established peripheral arterial disease. The main measure of effectiveness was how many patients experienced a new 'ischaemic event' (heart attack, ischaemic stroke or death) over one to three years.
In acute coronary syndrome, Clopidogrel BMS has been compared with placebo (a dummy treatment) in over 12,000 patients with non-ST segment elevation, 2,172 of whom had a stent inserted during the study (CURE study, lasting up to a year). Clopidogrel BMS has also been compared with placebo in two studies involving patients with ST segment elevation: CLARITY, which involved over 3,000 patients and lasted for up to eight days; and COMMIT, which involved almost 46,000 patients and in which the patients received Clopidogrel BMS with or without metoprolol (another medicine used for heart problems or high blood pressure) for up to four weeks. In the studies of acute coronary syndrome, all of the patients also took aspirin and the main measure of effectiveness was the number of patients experienced an 'event' such as a blocked artery, another heart attack or death during the study.

What benefit has Clopidogrel BMS shown during the studies?
Clopidogrel BMS was more effective than aspirin at preventing new ischaemic events. In CAPRIE, there were 939 events in the Clopidogrel BMS group, and 1,020 in the aspirin group. This corresponds to a relative reduction in risk of 9% compared with aspirin. This means that fewer patients will have new ischaemic events if they receive Clopidogrel BMS than if they receive aspirin. In other words, about 10 patients in 1,000 will avoid having a new ischaemic event two years after starting Clopidogrel BMS instead of aspirin.
In non-ST segment elevation acute coronary syndrome, the overall relative reduction in the risk of an event compared with placebo was 20%. There was also a reduction in the patients who had a stent inserted. In ST segment elevation myocardial infarction, fewer patients on Clopidogrel BMS had events than patients on placebo (262 against 377 in the CLARITY study, and 2,121 against 2,310 in the COMMIT study). This showed that Clopidogrel BMS reduces the risk of an event.

What is the risk associated with Clopidogrel BMS?
The most common side effects with Clopidogrel BMS (seen in between 1 and 10 patients in 100) are haematoma (a collection of blood under the skin), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), diarrhoea, abdominal pain (stomach ache), dyspepsia (heartburn), bruising and bleeding where the skin is punctured. For the full list of all side effects reported with Clopidogrel BMS, see the Package Leaflet.
Clopidogrel BMS should not be used in people who may be hypersensitive (allergic) to clopidogrel or any of the other ingredients. It must not be used in patients who have severe liver disease or a disease that may cause bleeding. For the full list of restrictions, see the Package Leaflet.

Why has Clopidogrel BMS been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Clopidogrel BMS's benefits are greater than its risks in adults for the prevention of atherothrombotic events. The Committee recommended that Clopidogrel BMS be given marketing authorisation.

Other information about Clopidogrel BMS:
The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel BMS to Bristol Myers Squibb Pharma EEIG on 16 July 2008. This authorisation was based on the authorisation granted to Iscover in 1998 ('informed consent').

The full EPAR for Clopidogrel BMS is available here.

This summary was last updated in 09-2009.