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EPAR summary for the public

Clopidogrel HCS

clopidogrel

This is a summary of the European public assessment report (EPAR) for Clopidogrel HCS. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Clopidogrel HCS.

What is Clopidogrel HCS?

Clopidogrel HCS is a blood-thinning medicine that contains the active substance clopidogrel. It is available as tablets (75 mg).

Clopidogrel HCS is a 'generic medicine'. This means that Clopidogrel HCS is similar to a 'reference medicine' already authorised in the European Union (EU) called Plavix. For more information on generic medicines, see the question-and-answer document here.

What is Clopidogrel HCS used for?

Clopidogrel HCS is used in adults to prevent problems caused by blood clots. Clopidogrel HCS can be given to the following groups of patients:

- patients who have recently had a myocardial infarction (heart attack). Clopidogrel HCS can be started between a few days and 35 days after the attack;
- patients who have had a recent ischaemic stroke (stroke caused by failure of the blood supply to part of the brain). Clopidogrel HCS 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 with acute coronary syndrome (a condition in which blood supply to the heart is reduced), 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).

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Clopidogrel HCS can be used in patients who are having a heart attack with '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.

- patients with atrial fibrillation (irregular rapid contractions of the upper chambers of the heart), when it should be given with aspirin. It is used in patients who have at least one risk factor for events such as a heart attack or stroke, cannot take vitamin-K antagonists (other medicines that prevent blood clots) and are at low risk of bleeding.

The medicine can only be obtained with a prescription.

How is Clopidogrel HCS used?

The standard dose of Clopidogrel HCS is one 75-mg tablet once a day. In acute coronary syndrome, treatment generally starts with a loading dose of four 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 unstable angina or non-Q-wave myocardial infarction). In acute coronary syndrome and atrial fibrillation, Clopidogrel HCS is used together with aspirin, the dose of which should not be higher than 100 mg.

How does Clopidogrel HCS work?

The active substance in Clopidogrel HCS, 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 HCS been studied?

Because Clopidogrel HCS is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Plavix. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Clopidogrel HCS?

Because Clopidogrel HCS is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as those of the reference medicine's.

Why has Clopidogrel HCS been approved?

The CHMP concluded that, in accordance with EU requirements, Clopidogrel HCS has been shown to have comparable quality and to be bioequivalent to Plavix. Therefore, the CHMP's view was that, as for Plavix, the benefit outweighs the identified risk. The Committee recommended that Clopidogrel HCS be given marketing authorisation.

Other information about Clopidogrel HCS

The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel HCS on 28 October 2010.

The full EPAR for Clopidogrel HCS can be found on the Agency's website: EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Clopidogrel HCS, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2015.