EMA/123618/2012
EMEA/H/C/001166

EPAR summary for the public

Clopidogrel Acino

clopidogrel

This is a summary of the European public assessment report (EPAR) for Clopidogrel Acino. 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 Acino.

What is Clopidogrel Acino?

Clopidogrel Acino is a medicine that contains the active substance clopidogrel. It is available as tablets (75 mg).

Clopidogrel Acino is a 'generic medicine'. This means that Clopidogrel Acino 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 Acino used for?

Clopidogrel Acino is used in adults to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries). Clopidogrel Acino can be given to the following groups of patients:

- patients who have recently had a myocardial infarction (heart attack). Clopidogrel Acino 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 Acino 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

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inserted (a short tube placed in an artery to prevent it closing up). Clopidogrel Acino can be used in patients who are having myocardial infarction with 'ST segment elevation' (an abnormal reading on the electrocardiogram or ECG) 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 Acino used?

The standard dose of Clopidogrel Acino is one 75 mg tablet once a day. In acute coronary syndrome, Clopidogrel Acino is used together with aspirin and treatment generally starts with a loading dose of 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).

How does Clopidogrel Acino work?

The active substance in Clopidogrel Acino, 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 Acino been studied?

Because Clopidogrel Acino is a generic medicine, studies 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 Acino?

Because Clopidogrel Acino 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.

Why has Clopidogrel Acino been approved?

The CHMP concluded that, in accordance with EU requirements, Clopidogrel Acino 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 Acino be given marketing authorisation.

Other information about Clopidogrel Acino

The European Commission granted a marketing authorisation valid throughout the EU for Clopidogrel Acino on 28 July 2009.

The full EPAR for Clopidogrel Acino can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about

treatment with Clopidogrel Acino, 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 02-2012.