EMA/670864/2012
EMEA/H/C/001165

EPAR summary for the public

Clopidogrel ratiopharm GmbH

clopidogrel

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

What is Clopidogrel ratiopharm GmbH?

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

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

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

- patients who have recently had a myocardial infarction (heart attack). Clopidogrel ratiopharm GmbH 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 ratiopharm GmbH can be started between seven days and six months after the stroke;
- patients with peripheral arterial disease (problems with blood flow in the arteries);

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- 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 ratiopharm GmbH 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 ratiopharm GmbH used?

The standard dose of Clopidogrel ratiopharm GmbH is one 75 mg tablet once a day. In acute coronary syndrome, Clopidogrel ratiopharm GmbH 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 ratiopharm GmbH work?

The active substance in Clopidogrel ratiopharm GmbH, 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 ratiopharm GmbH been studied?

Because Clopidogrel ratiopharm GmbH is a generic medicine, studies in patients 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 ratiopharm GmbH?

Because Clopidogrel ratiopharm GmbH is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as the reference medicine’s.

Why has Clopidogrel ratiopharm GmbH been approved?

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

Other information about Clopidogrel ratiopharm GmbH

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

The full EPAR for Clopidogrel ratiopharm GmbH 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 ratiopharm GmbH, 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 11-2012.