European Medicines Agency

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Clopidogrel DURA
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 for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Clopidogrel DURA?
Clopidogrel DURA is a medicine that contains the active substance clopidogrel. It is available as pink, round tablets (75 mg).
Clopidogrel DURA is a 'generic medicine'. This means that Clopidogrel DURA 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 DURA used for?
Clopidogrel DURA is used in adults to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries). Clopidogrel DURA can be given to the following groups of patients:
- patients who have recently had a myocardial infarction (heart attack). Clopidogrel DURA 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 DURA can be started between seven days and six months after the stroke;
- patients with peripheral arterial disease (problems with blood flow in the arteries).

The medicine can only be obtained with a prescription.

How is Clopidogrel DURA used?
The standard dose of Clopidogrel DURA is one 75 mg tablet once a day, taken with or without food.

How does Clopidogrel DURA work?
The active substance in Clopidogrel DURA, 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.

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How has Clopidogrel DURA been studied?
Because Clopidogrel DURA 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 benefit and risk of Clopidogrel DURA?
Because Clopidogrel DURA is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Clopidogrel DURA been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Clopidogrel DURA 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 DURA be given marketing authorisation.

Other information about Clopidogrel DURA:
The European Commission granted a marketing authorisation valid throughout the EU for Clopidogrel DURA to Mylan dura GmbH on 21 September 2009.

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

This summary was last updated in 07-2009.