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EPAR summary for the public

Clopidogrel Teva Pharma B.V.

clopidogrel

This document is a summary of the European public assessment report (EPAR) for Clopidogrel Teva Pharma B.V. 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 Teva Pharma B.V.

What is Clopidogrel Teva Pharma B.V.?

Clopidogrel Teva Pharma B.V. is a medicine that contains the active substance clopidogrel. It is available as pink, capsule-shaped tablets (75 mg).

Clopidogrel Teva Pharma B.V. is a 'generic medicine'. This means that Clopidogrel Teva Pharma B.V. 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 Teva Pharma B.V. used for?

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

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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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 Teva Pharma B.V. 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.

The medicine can only be obtained with a prescription.

How is Clopidogrel Teva Pharma B.V. used?

The standard dose of Clopidogrel Teva Pharma B.V. is one 75-mg tablet once a day, taken with or without food. In acute coronary syndrome, Clopidogrel Teva Pharma B.V. is used together with aspirin and 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 non-ST segment elevation syndrome).

Clopidogrel Teva Pharma B.V. is converted into its active form in the body. For genetic reasons, some patients may not be able to convert Clopidogrel Teva Pharma B.V. 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.

How does Clopidogrel Teva Pharma B.V. work?

The active substance in Clopidogrel Teva Pharma B.V., 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 Teva Pharma B.V. been studied?

Because Clopidogrel Teva Pharma B.V. 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 benefit and risk of Clopidogrel Teva Pharma B.V.?

Because Clopidogrel Teva Pharma B.V. 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 Teva Pharma B.V. been approved?

The CHMP concluded that, in accordance with EU requirements, Clopidogrel Teva Pharma B.V. 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 Teva Pharma B.V. be given marketing authorisation.

Other information about Clopidogrel Teva Pharma B.V.:

The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel Teva Pharma B.V. to Teva Pharma B.V. on 16 June 2011. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Clopidogrel Teva Pharma B.V. can be found on the Agency's website under EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Clopidogrel Teva Pharma B.V., 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 08-2010.