EMA/141297/2016
EMEA/H/C/001133

EPAR summary for the public

Clopidogrel Teva Pharma[1]

clopidogrel

Medicinal product no longer authorised

This document is a summary of the European Public Assessment Report (EPAR) for Clopidogrel Teva Pharma. 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.

What is Clopidogrel Teva Pharma?

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

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

Clopidogrel Teva Pharma is used to prevent problems caused by blood clots in adults who have:

- recently had a myocardial infarction (heart attack). Clopidogrel Teva Pharma can be started between a few days and 35 days after the attack;
- recently had an ischaemic stroke (stroke caused by failure of the blood supply to part of the brain). Clopidogrel Teva Pharma can be started between seven days and six months after the stroke;
- peripheral arterial disease (problems with blood flow in the arteries);
- a condition known as 'acute coronary syndrome', when it should be given with aspirin (another medicine that prevents blood clots). Acute coronary syndrome is a group of heart problems that include heart attacks and unstable angina (a severe type of chest pain). Some of these patients may have had a stent (a short tube) placed in an artery to prevent it from closing up;

[1] Previously known as Clopidogrel HCS.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2016. Reproduction is authorised provided the source is acknowledged.

- atrial fibrillation (irregular rapid contractions of the upper chambers of the heart), when it should be given with aspirin. It is used in those patients who have at least one risk factor for vascular 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 Teva Pharma used?

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

How does Clopidogrel Teva Pharma work?

The active substance in Clopidogrel Teva Pharma, 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 been studied?

Because Clopidogrel Teva Pharma 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 benefit and risk of Clopidogrel Teva Pharma?

Because Clopidogrel Teva Pharma 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 Teva Pharma been approved?

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

Other information about Clopidogrel Teva Pharma:

The European Commission granted a marketing authorisation valid throughout the EU for Clopidogrel HCS on 21 September 2009. The name of the medicine was changed to Clopidogrel Teva Pharma on 20 October 2009.

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

Medicinal product no longer authorised

treatment with Clopidogrel Teva Pharma, 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 02-2016.

Medicinal product no longer authorised