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EPAR summary for the public

Clopidogrel Krka d.d.[1]

clopidogrel

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

What is Clopidogrel Krka d.d.?

Clopidogrel Krka d.d. is a medicine that contains the active substance clopidogrel. It is available as pink, round tablets (75 mg).

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

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

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

[1] Previously known as Zopya.

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
An agency of the European Union

The medicine can only be obtained with a prescription.

How is Clopidogrel Krka d.d. used?

The standard dose of Clopidogrel Krka d.d. is one 75 mg tablet once a day, taken with or without food.

How does Clopidogrel Krka d.d. work?

The active substance in Clopidogrel Krka d.d., 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 Krka d.d. been studied?

Because Clopidogrel Krka d.d. 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 Krka d.d.?

Because Clopidogrel Krka d.d. 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 Krka d.d. been approved?

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

Other information about Clopidogrel Krka d.d.

The European Commission granted a marketing authorisation valid throughout the EU for Zopya on 21 September 2009. The name of the medicine was changed to Clopidogrel Krka d.d. on 18 May 2011.

The full EPAR for Clopidogrel Krka d.d. 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 Krka d.d., 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 12-2011.