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**EPAR summary for the public**

# Clopidogrel Krka

clopidogrel

This is a summary of the European public assessment report (EPAR) for Clopidogrel Krka. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Clopidogrel Krka.

For practical information about using Clopidogrel Krka, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Clopidogrel Krka and what is it used for?

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

- recently had a myocardial infarction (heart attack). Clopidogrel Krka 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 Krka 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;
- 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.

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Clopidogrel Krka is a 'generic medicine'. This means that Clopidogrel Krka 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.

Clopidogrel Krka contains the active substance clopidogrel.

## How is Clopidogrel Krka used?

Clopidogrel Krka is available as tablets containing 75 mg clopidogrel. The standard dose is one 75-mg tablet once a day.

In acute coronary syndrome, 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 unstable angina or 'non-Q-wave' myocardial infarction).

In acute coronary syndrome and atrial fibrillation, Clopidogrel Krka is used together with aspirin, the dose of which should not be higher than 100 mg.

Clopidogrel Krka can only be obtained with a prescription.

## How does Clopidogrel Krka work?

The active substance in Clopidogrel Krka, 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 been studied?

Because Clopidogrel Krka 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 benefits and risks of Clopidogrel Krka?

Because Clopidogrel Krka is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

## Why is Clopidogrel Krka approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Clopidogrel Krka has been shown to have comparable quality and to be bioequivalent to Plavix. Therefore, the Agency's view was that, as for Plavix, the benefit outweighs the identified risk. The Agency recommended that Clopidogrel Krka be approved for use in the EU.

## What measures are being taken to ensure the safe and effective use of Clopidogrel Krka?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Clopidogrel Krka have been included in the summary of product characteristics and the package leaflet.

## Other information about Clopidogrel Krka

The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel Krka on 23 September 2009.

The full EPAR for Clopidogrel Krka 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, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.