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EPAR summary for the public

Clopidogrel ratiopharm

clopidogrel

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

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

What is Clopidogrel ratiopharm and what is it used for?

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

- patients who have recently had a myocardial infarction (heart attack). Clopidogrel ratiopharm 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 ratiopharm can be started between seven days and six months after the stroke;
- patients with peripheral arterial disease (problems with blood flow in the arteries);
- patients with acute coronary syndrome (a condition in which blood supply to the heart is reduced), including patients who have had a stent inserted (a short tube placed in an artery to prevent it closing up); the medicine should be given with aspirin (another medicine that prevents blood clots). Clopidogrel ratiopharm 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.

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

Clopidogrel ratiopharm can also be used to prevent problems caused by blood clots in adults with atrial fibrillation (irregular rapid contractions of the upper chambers of the heart), when it should be given with aspirin. It is used in patients who have at least one risk factor for 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.

Clopidogrel ratiopharm is a 'generic medicine'. This means that Clopidogrel ratiopharm 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 ratiopharm contains the active substance clopidogrel.

How is Clopidogrel ratiopharm used?

Clopidogrel ratiopharm 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 ratiopharm is used together with aspirin, the dose of which should not be higher than 100 mg.

Clopidogrel ratiopharm can only be obtained with a prescription.

How does Clopidogrel ratiopharm work?

The active substance in Clopidogrel ratiopharm, 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 ratiopharm been studied?

Because Clopidogrel ratiopharm 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 ratiopharm?

Because Clopidogrel ratiopharm 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 ratiopharm approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Clopidogrel ratiopharm 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 ratiopharm be approved for use in the EU.

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

A risk management plan has been developed to ensure that Clopidogrel ratiopharm is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Clopidogrel ratiopharm, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Clopidogrel ratiopharm

The European Commission granted a marketing authorisation valid throughout the European Union for Clopidogrel ratiopharm on 19 February 2015.

The full EPAR and risk management plan summary for Clopidogrel ratiopharm 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 ratiopharm, 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 02-2015.