

Clopidogrel Qualimed *clopidogrel*

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Clopidogrel Qualimed?

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

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

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

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

The medicine can only be obtained with a prescription.

How is Clopidogrel Qualimed used?

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

How does Clopidogrel Qualimed work?

The active substance in Clopidogrel Qualimed, 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 Qualimed been studied?

Because Clopidogrel Qualimed 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 benefit and risk of Clopidogrel Qualimed?

Because Clopidogrel Qualimed 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 Qualimed been approved?

The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Clopidogrel Qualimed 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 Qualimed be given marketing authorisation.

Other information about Clopidogrel Qualimed:

The European Commission granted a marketing authorisation valid throughout the EU for Clopidogrel Qualimed to Qualimed on 23 September 2009.

The full EPAR for Clopidogrel Qualimed can be found [here](#).

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 07-2009.

Medicinal product no longer authorised