

Clopidogrel Sandoz *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 Sandoz?

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

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

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

- patients who have recently had a myocardial infarction (heart attack). Clopidogrel Sandoz 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 Sandoz 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 Sandoz used?

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

How does Clopidogrel Sandoz work?

The active substance in Clopidogrel Sandoz, 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 Sandoz been studied?

Because Clopidogrel Sandoz 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 Sandoz?

Because Clopidogrel Sandoz 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 Sandoz been approved?

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

Other information about Clopidogrel Sandoz:

The European Commission granted a marketing authorisation valid throughout the EU for Clopidogrel Sandoz to Acino Pharma GmbH on 21 september 2009.

The full EPAR for Clopidogrel Sandoz 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