



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Clopidogrel Taw Pharma<sup>1</sup> (*clopidogrel*)

An overview of Clopidogrel Taw Pharma and why it is authorised in the EU

### What is Clopidogrel Taw Pharma and what is it used for?

Clopidogrel Taw Pharma is a medicine used to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) in adults who have:

- recently had a myocardial infarction (heart attack). Clopidogrel Taw Pharma can be started between a few days and 35 days after the attack;
- recently had an ischaemic stroke (stroke caused by insufficient blood supply to part of the brain). Clopidogrel Taw Pharma 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 unstable angina (a severe type of chest pain) and certain types of heart attack. Some of these patients may have had a stent (a short tube) inserted into an artery to prevent it from closing up.

Clopidogrel Taw Pharma is also 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 Taw Pharma contains the active substance clopidogrel and is a 'generic medicine'. This means that Clopidogrel Taw Pharma contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Plavix. For more information on generic medicines, see the question-and-answer document [here](#).

### How is Clopidogrel Taw Pharma used?

Clopidogrel Taw Pharma is available as tablets. The standard dose is 75 mg once a day.

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<sup>1</sup> Previously known as Clopidogrel Mylan.



In acute coronary syndrome, treatment generally starts with a loading dose of 300 mg. This is then followed by the standard 75 mg dose once a day for between 4 weeks and up to 12 months.

Clopidogrel Taw Pharma can only be obtained with a prescription.

For more information about using Clopidogrel Taw Pharma, see the package leaflet or contact your doctor or pharmacist.

## **How does Clopidogrel Taw Pharma work?**

The active substance in Clopidogrel Taw Pharma, clopidogrel, is an antiplatelet medicine. This means that it helps to prevent components in the blood called platelets from sticking together and forming clots. Clopidogrel blocks a substance called ADP from attaching to a receptor (target) on the surface of platelets. 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 Taw Pharma been studied?**

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Plavix, and do not need to be repeated for Clopidogrel Taw Pharma.

As for every medicine, the company provided data on the quality of Clopidogrel Taw Pharma. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

## **What are the benefits and risks of Clopidogrel Taw Pharma?**

Because Clopidogrel Taw Pharma 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 Taw Pharma authorised in the EU?**

The European Medicines Agency concluded that, in accordance with EU requirements, Clopidogrel Taw Pharma has been shown to have comparable quality and to be bioequivalent to Plavix. Therefore, the Agency's view was that, as for Plavix, the benefits of Clopidogrel Taw Pharma outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Clopidogrel Taw Pharma are continuously monitored. Suspected side effects reported with Clopidogrel Taw Pharma are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Clopidogrel Taw Pharma**

Clopidogrel Mylan received a marketing authorisation valid throughout the EU on 21 September 2009. The name of the medicine was changed to Clopidogrel Taw Pharma on 1 October 2021.

Further information on Clopidogrel Taw Pharma can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/clopidogrel-taw-pharma](https://ema.europa.eu/medicines/human/EPAR/clopidogrel-taw-pharma). Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 11-2021.