



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Clpidogrel/Acetylsalicylic acid Mylan (*clpidogrel / acetylsalicylic acid*)

An overview of Clpidogrel/Acetylsalicylic acid Mylan and why it is authorised in the EU

What is Clpidogrel/Acetylsalicylic acid Mylan and what is it used for?

Clpidogrel/Acetylsalicylic acid Mylan is a medicine used to prevent problems caused by blood clots and hardening of the arteries, such as a heart attack, in adults who are already taking both clpidogrel and acetylsalicylic acid as separate tablets. It can be used in the following groups of patients who have a condition known as 'acute coronary syndrome':

- patients who have unstable angina (a severe type of chest pain) or who have had a heart attack with no 'ST-segment elevation' (an abnormal reading on an electrocardiogram), including those who are having a stent (a short tube) inserted into an artery to prevent it from closing up;
- patients being treated for heart attack with ST-segment elevation, when the doctor thinks that they would benefit from thrombolytic treatment (treatment to dissolve blood clots).

Clpidogrel/Acetylsalicylic acid Mylan contains two active substances, clpidogrel and acetylsalicylic acid (also known as aspirin) and is a 'generic medicine'. This means that Clpidogrel/Acetylsalicylic acid Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called DuoPlavin. For more information on generic medicines, see the question-and-answer document [here](#).

How is Clpidogrel/Acetylsalicylic acid Mylan used?

The medicine is available as tablets containing 75 mg clpidogrel, either with 75 mg or 100 mg acetylsalicylic acid and can only be obtained with a prescription. The medicine is taken as one tablet once a day instead of the clpidogrel and acetylsalicylic acid tablets that the patient has already been taking separately.

For more information about using Clpidogrel/Acetylsalicylic acid Mylan, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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How does Clopidogrel/Acetylsalicylic acid Mylan work?

Both active substances in the medicine, clopidogrel and acetylsalicylic acid, are antiplatelet medicines. This means that they help to prevent components in the blood called platelets from sticking together and forming clots, thus helping to prevent another heart attack.

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. Acetylsalicylic acid blocks an enzyme called prostaglandin cyclo-oxygenase. This reduces the production of a substance called thromboxane, which normally helps clots to form by attaching platelets together. The combination of the two active substances reduces the risk of blood clots forming more than either medicine alone.

Both active substances have been available in the EU for a number of years. Clopidogrel has been authorised since 1998 as an antiplatelet medicine, and is often used in combination with acetylsalicylic acid. Acetylsalicylic acid has been available for over 100 years.

How has Clopidogrel/Acetylsalicylic acid Mylan been studied?

Studies on the benefits and risks of the active substances in the authorised uses have already been carried out with the reference medicine, DuoPlavin, and do not need to be repeated for Clopidogrel/Acetylsalicylic acid Mylan.

As for every medicine, the company provided studies on the quality of Clopidogrel/Acetylsalicylic acid Mylan. 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/Acetylsalicylic acid Mylan?

Because Clopidogrel/Acetylsalicylic acid Mylan 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/Acetylsalicylic acid Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Clopidogrel/Acetylsalicylic acid Mylan has been shown to have comparable quality and to be bioequivalent to DuoPlavin. Therefore, the Agency's view was that, as for DuoPlavin, the benefits of Clopidogrel/Acetylsalicylic acid Mylan 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/Acetylsalicylic acid Mylan?

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

As for all medicines, data on the use of Clopidogrel/Acetylsalicylic acid Mylan are continuously monitored. Side effects reported with Clopidogrel/Acetylsalicylic acid Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Clopidogrel/Acetylsalicylic acid Mylan

Clopidogrel/Acetylsalicylic acid Mylan received a marketing authorisation valid throughout the EU on 09 January 2020.

Further information on Clopidogrel/Acetylsalicylic acid Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/clopidogrel-acetylsalicylic-acid-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 01-2020.