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Clopidogrel Viatris[1] (*clopidogrel*)

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

What is Clopidogrel Viatris and what is it used for?

Clopidogrel Viatris 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 Viatris 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 Viatris 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 is given with aspirin (another medicine that prevents blood clots). Acute coronary syndrome is a group of heart problems that include heart attack and unstable angina (a severe type of chest pain). Some of these patients may have had a stent (a short tube) placed in an artery to prevent it from closing up.

Clopidogrel Viatris 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 is given with aspirin. It is used in those patients who have at least one risk factor for vascular 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 Viatris contains the active substance clopidogrel and is a 'generic medicine'. This means that Clopidogrel Viatris 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 Viatris used?

Clopidogrel Viatris is available as tablets. The standard dose is 75 mg once a day. 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 Viatris can only be obtained with a prescription.

[1] Initially known as Clopidogrel Mylan Pharma and subsequently as Clopidogrel Apotex and then Clopidogrel Taw Pharma.

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 An agency of the European Union

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

How does Clopidogrel Viatris work?

The active substance in Clopidogrel Viatris, 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 Viatris 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 Viatris.

As for every medicine, the company provided data on the quality of Clopidogrel Viatris. The company also carried out studies 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 Viatris?

Because Clopidogrel Viatris 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 Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Clopidogrel Viatris 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 Viatris 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 Viatris?

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

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

Other information about Clopidogrel Viatris:

Clopidogrel Mylan Pharma received a marketing authorisation valid throughout the EU on 16 October 2009. The name of the medicine was changed to Clopidogrel Apotex on 20 January 2010, to Clopidogrel Taw Pharma on 28 January 2021 and to Clopidogrel Viatris on 6 October 2021

Further information on Clopidogrel Viatris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/clopidogrel-viatris. Information on the reference medicine can also be found on the Agency's website.

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