EMA/203583/2018
EMEA/H/C/004644

Prasugrel Mylan (*prasugrel*)

An overview of Prasugrel Mylan and why it is authorised in the EU

What is Prasugrel Mylan and what is it used for?

Prasugrel Mylan is taken together with aspirin to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) in patients with acute coronary syndrome who are undergoing percutaneous coronary intervention. Acute coronary syndrome is a group of conditions in which blood supply in the vessels supplying the heart is interrupted so heart tissue cannot work properly or dies. It includes unstable angina (a severe type of chest pain) and heart attack. Percutaneous coronary intervention is a procedure used to unblock the blood vessels supplying the heart.

Prasugrel Mylan contains the active substance prasugrel and is a 'generic medicine'. This means that Prasugrel Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Efient. For more information on generic medicines, see the question-and-answer document here.

How is Prasugrel Mylan used?

Prasugrel Mylan is available as tablets (5 and 10 mg) and can only be obtained with a prescription. Prasugrel Mylan treatment starts with one 60-mg dose. This is then followed by 10 mg taken once a day, except in patients weighing less than 60 kg, who should take 5 mg once a day. Patients taking Prasugrel Mylan should also take aspirin as prescribed by their doctors. It is recommended that treatment with Prasugrel Mylan and aspirin continue for up to a year.

The use of Prasugrel Mylan is not recommended in patients over 75 years of age, unless the doctor has carefully considered its benefits and risks, and regards treatment with Prasugrel Mylan as necessary. In this case, the patient should take 5 mg daily following a 60-mg starting dose.

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

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How does Prasugrel Mylan work?

The active substance in Prasugrel Mylan, prasugrel, is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. Blood clots are caused by special cells in the blood, the platelets, sticking together (aggregating). Prasugrel stops the platelets aggregating by blocking a substance called ADP from binding to a receptor (target) on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent a heart attack or a stroke.

How has Prasugrel Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Efient, and do not need to be repeated for Prasugrel Mylan.

As for every medicine, the company provided studies on the quality of Prasugrel Mylan. 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 Prasugrel Mylan?

Because Prasugrel 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 Prasugrel Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Prasugrel Mylan has been shown to have comparable quality and to be bioequivalent to Efient. Therefore, the Agency's view was that, as for Efient, the benefit of Prasugrel Mylan outweighs the identified risk and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Prasugrel Mylan?

The company that markets Prasugrel Mylan will make sure that educational materials are available for doctors who will treat patients with the medicine. The materials will include information on how to prescribe the medicine safely and remind doctors that the medicine is not recommended for patients over the age of 75 years.

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

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

Other information about Prasugrel Mylan

Prasugrel Mylan received a marketing authorisation valid throughout the EU on 16 May 2018.

Further information on Prasugrel Mylan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2018.