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Rivaroxaban Mylan (*rivaroxaban*)

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

What is Rivaroxaban Mylan and what is it used for?

Rivaroxaban Mylan is an anticoagulant medicine (a medicine that prevents blood clotting) used:

- to treat deep vein thrombosis (DVT, a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent DVT and pulmonary embolism from re-occurring in adults;
- to prevent venous thromboembolism (VTE, the formation of blood clots in the veins) in adults who are undergoing surgery to replace a hip or knee;
- to treat VTE and prevent VTE from re-occurring in children and adolescents aged less than 18 years weighing more than 30 kg;
- to prevent stroke (caused by a clot in a blood vessel in the brain) and systemic embolism (a clot in other blood vessels) in adults with non-valvular atrial fibrillation (irregular rapid contractions of the upper chambers of the heart);
- to prevent atherothrombotic events (such as heart attack, stroke or death from heart disease) in adults:
  - after an acute coronary syndrome, when it is used with an antiplatelet medicine (which prevents the formation of blood clots). Acute coronary syndrome consists of conditions such as unstable angina (a severe type of chest pain) and heart attack;
  - at high risk of ischaemic events (problems caused by restricted blood supply) who have coronary artery disease (disease caused by obstructed blood supply to the heart muscle) or peripheral artery disease (disease caused by defective blood flow in the arteries). It is used with aspirin.

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

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How is Rivaroxaban Mylan used?

Rivaroxaban Mylan is available as tablets of various strengths. The dose and duration of treatment with Rivaroxaban Mylan depend on what it is being used for and the patient's risk of bleeding. For children, the form, dose and duration of treatment also depend on the patient's age and weight. Rivaroxaban Mylan is given at a lower dose when used in combination with an antiplatelet medicine such as aspirin, clopidogrel or ticlopidine. The doctor will regularly evaluate the benefits of ongoing treatment against the risk of excessive or internal bleeding.

The medicine can only be obtained with a prescription. For more information about using Rivaroxaban Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Rivaroxaban Mylan work?

The active substance in Rivaroxaban Mylan, rivaroxaban, is a 'factor Xa inhibitor'. This means that it blocks factor Xa, an enzyme that is involved in the production of thrombin. Thrombin is central to the process of blood clotting. By blocking factor Xa, the levels of thrombin decrease, which reduces the risk of blood clots forming in the veins and arteries, and also treats existing clots.

How has Rivaroxaban Mylan 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, Xarelto, and do not need to be repeated for Rivaroxaban Mylan.

As for every medicine, the company provided data on the quality of Rivaroxaban 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 Rivaroxaban Mylan?

Because Rivaroxaban 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 Rivaroxaban Mylan authorised in the EU?

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

The company that markets Rivaroxaban Mylan will provide an educational pack for doctors who prescribe Rivaroxaban Mylan, containing important safety information including on the risk of bleeding during treatment with Rivaroxaban Mylan and how to manage this risk. In addition, prescribers will receive a patient alert card to give to patients receiving Rivaroxaban Mylan containing key safety reminders for patients.

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

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

Other information about Rivaroxaban Mylan

Rivaroxaban Mylan received a marketing authorisation valid throughout the EU on 12 November 2021.

Further information on Rivaroxaban Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rivaroxaban-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 11-2021.