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Rivaroxaban Accord (*rivaroxaban*)

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

What is Rivaroxaban Accord and what is it used for?

Rivaroxaban Accord is an anticoagulant medicine (a medicine that prevents blood clotting) used in adults:

- 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-occuring;
- to prevent venous thromboembolism (VTE, the formation of blood clots in the veins) in patients who are undergoing surgery to replace a hip or knee;
- to prevent stroke (caused by a blood clot in the brain) and systemic embolism (a blood clot in another organ) in patients 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 patients:
    - 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 Accord contains the active substance rivaroxaban.

Rivaroxaban Accord is a 'generic medicine'. This means that Rivaroxaban Accord 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 Accord used?

Rivaroxaban Accord is available as tablets (2.5, 10, 15 and 20 mg). The dose and duration of treatment with Rivaroxaban Accord depend on what it is being used for and the patient's risk of bleeding. It is given at a lower dose (2.5 mg twice daily) when used in combination with an antiplatelet medicine such as acetylsalicylic acid (aspirin) 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 Accord, see the package leaflet or contact your doctor or pharmacist.

How does Rivaroxaban Accord work?

The active substance in Rivaroxaban Accord, 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 Accord 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 Accord.

As for every medicine, the company provided studies on the quality of Rivaroxaban Accord. 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 Accord?

Because Rivaroxaban Accord 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 Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Rivaroxaban Accord 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 Accord 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 Accord?

The company that markets Rivaroxaban Accord will provide an educational pack for doctors who prescribe Rivaroxaban Accord, containing important safety information including on the risk of bleeding during treatment with Rivaroxaban Accord and how to manage this risk. In addition, prescribers will receive a patient alert card to give to patients receiving Rivaroxaban Accord 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 Accord have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Rivaroxaban Accord

Rivaroxaban Accord received a marketing authorisation valid throughout the EU on 16 November 2020.

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

This overview was last updated in 11-2020.