Summary Public Assessment Report

Generics

Rivaroxaban Medreg
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Rivaroxaban, 2.5 mg, 10 mg, 15 mg, 20 mg, film-coated tablets

This is a summary of the public assessment report (PAR) for Rivaroxaban Medreg. It explains how Rivaroxaban Medreg was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Rivaroxaban Medreg.

For practical information about using Rivaroxaban Medreg, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rivaroxaban Medreg and what is it used for?

Rivaroxaban Medreg is a 'generic medicine'. This means that Rivaroxaban Medreg is similar to a 'reference medicine' already authorised in the European Union (EU) called Xarelto.

Rivaroxaban Medreg 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 recurring 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 prevent stroke (caused by a blood clot in the brain) and systemic embolism (a blood clot in another organ) 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 acetylsalicylic acid (aspirin).

How does Rivaroxaban Medreg work?

The active substance in Rivaroxaban Medreg, 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 treats existing clots.

How is Rivaroxaban Medreg used?

The pharmaceutical form of Rivaroxaban Medreg is film-coated tablet, and the route of administration is oral.

The dose and duration of treatment with Rivaroxaban Medreg depend on what it is being used for and the patient's risk of bleeding.
Rivaroxaban Medreg is given at a lower dose (2.5 mg twice daily) when used in combination with an antiplatelet medicine such as acetylsalicylic acid (aspirin), clopidogrel or ticlopidine. The doctor will regularly evaluate the benefits of ongoing treatment against the risk of excessive or internal bleeding.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Rivaroxaban Medreg have been shown in studies?

Because Rivaroxaban Medreg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Xarelto. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Rivaroxaban Medreg?

Because Rivaroxaban Medreg is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

Why is Rivaroxaban Medreg approved?

It was concluded that, in accordance with EU requirements, Rivaroxaban Medreg has been shown to have comparable quality and to be bioequivalent to Xarelto. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Xarelto, the benefits are greater than its risk except the use in paediatric population and recommended that it can be approved for use.

Even though the reference medicine Xarelto 15 mg and 20 mg is indicated also in children and adolescents, Rivaroxaban Medreg is not due to presence of some azo dyes (sunset yellow FCF) in film-coating of the tablet. There are some safety concerns with respect to use of azo dyes in paediatric population and therefore it was decided that this generic medicine is not suitable for children and adolescents.

What measures are being taken to ensure the safe and effective use of Rivaroxaban Medreg?

A risk management plan has been developed to ensure that Rivaroxaban Medreg is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rivaroxaban Medreg, including the appropriate precautions to be followed by healthcare professionals and patients.

An educational pack is provided to all physicians who will prescribe/use this medicine. The educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with rivaroxaban and providing guidance on how to manage that risk.
The physician educational pack contains:
• the summary of product characteristics
• prescriber guide
• patient alert cards

Patients should always keep patient alert card with them and present the card to every physician or dentist prior to their treatment.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Rivaroxaban Medreg

The marketing authorisation for Rivaroxaban Medreg was granted on 16 December 2023.

The full PAR for Rivaroxaban Medreg can be found on the website. For more information about treatment with Rivaroxaban Medreg, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 04-2025.