

Summary Public Assessment Report

Rivaroxaban Jubilant (rivaroxaban)

SE/H/2548/01-04/DC

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rivaroxaban

Film-coated tablet, 15 mg and 20 mg

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Rivaroxaban Jubilant and what is it used for?

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

The product is used in the treatment of:

- prevent blood clots in brain (stroke) and other blood vessels in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation.
- treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

Rivaroxaban Jubilant is used in children and adolescents below 18 years and with a body weight of 30 kg or more to:

treat blood clots and prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs, following initial treatment of at least 5 days with injectable medicines used to treat blood clots.

How does Rivaroxaban Jubilant work?

Rivaroxaban Jubilant belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

How is Rivaroxaban Jubilant used?

The pharmaceutical form is film-coated tablet, for oral use.

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

The medicine can only be obtained with a prescription in Sweden.

What benefits of Rivaroxaban Jubilant have been shown in studies?

Because the product 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 from Rivaroxaban Jubilant?

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

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Rivaroxaban Jubilant approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xarelto, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Rivaroxaban Jubilant?”

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

A risk management plan has been developed to ensure that the product 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, including the appropriate precautions to be followed by healthcare professionals and patients.

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

The MAH shall provide an educational pack prior to launch, targeting all physicians who are expected to prescribe/use Rivaroxaban Jubilant. The educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with Rivaroxaban Jubilant and providing guidance on how to manage that risk.

For more details, please see the full PAR for Rivaroxaban Jubilant on the following website: [MRI - Home](#).

Other information about Rivaroxaban Jubilant

The full PAR for Rivaroxaban Jubilant can be found on the following website: [MRI - Home](#). For more information about treatment with Rivaroxaban Jubilant, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.