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Svariya (*rivaroxaban*)

An overview of Svariya and why it is authorised in the EU

What is Svariya and what is it used for?

Svariya 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 treat VTE and prevent VTE from recurring in children and adolescents aged less than 18 years;
- 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).

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

How is Svariya used?

Svariya is available as a film to be placed on the tongue, where it will disperse rapidly. The dose and duration of treatment with Svariya depend on what it is being used for and the patient's risk of bleeding. For children, the dose and duration of treatment also depend on the patient's age and weight.

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

How does Svariya work?

The active substance in Svariya, 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

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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 Svariya 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 R Svariya.

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

Because Svariya 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 Svariya authorised in the EU?

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Svariya have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Xarelto also apply to Svariya where appropriate.

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

Other information about Svariya

Svariya received a marketing authorisation valid throughout the EU on 21 November 2025.

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

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