LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Apixaban Devatis
(apixaban)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

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Apixaban Devatis
apixaban

Film-coated tablet, 2,5 mg, 5 mg

This is a summary of the public assessment report (PAR) for Apixaban Devatis. 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 Apixaban Devatis 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 Eliquis.

Apixaban Devatis 2,5 mg film-coated tablet is used in adults:
- to prevent blood clots (deep vein thrombosis [DVT]) from forming after hip or knee replacement operations. After an operation to the hip or knee you may be at a higher risk of developing blood clots in your leg veins. This can cause the legs to swell, with or without pain. If a blood clot travels from your leg to your lungs, it can block blood flow causing breathlessness, with or without chest pain. This condition (pulmonary embolism) can be life-threatening and requires immediate medical attention.

- to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.

- to 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.

Apixaban Devatis 5 mg film-coated tablet is used in adults:
- to prevent a blood clot from forming in the heart in patients with an irregular heart beat (atrial fibrillation) and at least one additional risk factor. Blood clots may break off and travel to the brain and lead to a stroke or to other organs and prevent normal blood flow to that organ (also known as a systemic embolism). A stroke can be life-threatening and requires immediate medical attention.

- to 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.

Apixaban Devatis 2,5 mg film-coated tablet and 5 mg film-coated tablet is used in children aged 28 days to less than 18 years to treat blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs.

How does Apixaban Devatis work?
Apixaban Devatis contains the active substance apixaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking factor Xa, which is an important component of blood clotting.

How is Apixaban Devatis 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 Apixaban Devatis 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, Eliquis. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Apixaban Devatis?
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 Apixaban Devatis approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Eliquis, 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 provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Apixaban Devatis?”

What measures are being taken to ensure the safe and effective use of Apixaban Devatis?
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 Marketing Authorization Holder shall ensure that all prescribing HPCs, patients and/or caregivers of paediatric patients who receive Apixaban Devatis have access to a Patient Card (provided within each medicine pack).

For more details, please see the full PAR for Apixaban Devatis on the following website: MRI - Home.

Other information about Apixaban Devatis

The full PAR for Apixaban Devatis can be found on the following website: MRI - Home. For more information about treatment with Apixaban Devatis, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.