LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Apixaban Glenmark
(apixaban)

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Summary Public Assessment Report

Apixaban Glenmark
apixaban

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

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

2,5 mg
Apixaban Glenmark 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 Glenmark is used in children aged 28 days to less than 18 years to treat blood clots and to prevent reoccurrence of blood clots in the veins or in the blood vessels of the lungs.

5 mg
Apixaban Glenmark 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 Glenmark is used in children aged 28 days to less than18 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 Glenmark work?

Apixaban Glenmark 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 Glenmark 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 Glenmark have been shown in studies?

Because the product is a generic medicine, studies 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 Glenmark?

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 Glenmark 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 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 Apixaban Glenmark?”

What measures are being taken to ensure the safe and effective use of Apixaban Glenmark?
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.

- **Additional risk minimisation measures (including educational material)**
  Details of proposed additional risk minimisation activities
  The Marketing Authorization holder shall ensure that all physicians who are expected to prescribe apixaban are provided with following educational material:
  • Summary of product characteristics
  • Patient Card

  All patients and/or caregivers of paediatric patients who receive Apixaban Glenmark shall be provided with a Patient Card (provided within each medicine pack).

  Key elements of Patient Card
  • Signs or symptoms of bleeding and when to seek attention from health care provider
  • Importance of treatment compliance
  • Necessity to carry the Patient Card with them at all times
  • The need to inform health care professionals that they are taking Apixaban Glenmark if they need to have any surgery or invasive procedures

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

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

This summary was last updated in 2026-04.