LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dabigatran etexilate DOC
(dabigatran etexilate mesilate)

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Summary Public Assessment Report

Dabigatran etexilate DOC
dabigatran etexilate mesilate

capsule, hard, 75 mg, 110 mg, 150 mg

This is a summary of the public assessment report (PAR) for Dabigatran etexilate DOC. 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 Dabigatran etexilate DOC 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 Pradaxa.

The product contains the active substance dabigatran etexilate and belongs to a group of medicines called anticoagulants. It works by blocking a substance in the body which is involved in blood clot formation.

Dabigatran etexilate 75 mg and 110 mg hard capsules are used in adults to prevent the formation of blood clots in the veins after knee or hip replacement surgery.

Dabigatran etexilate 110 mg and 150 mg hard capsules are used in adults to prevent blood clots in the brain (stroke) and other blood vessels in the body if the patient has a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor. They are also used in adults to treat blood clots in the veins of the legs and lungs and to prevent blood clots from reoccurring in the vein of the legs and lungs.

Dabigatran etexilate 75 mg, 110 mg and 150 mg hard capsules are used in children to treat blood clots and to prevent blood clots from reoccurring.

How does Dabigatran etexilate DOC work?

Dabigatran etexilate is a small molecule, a so called ´prodrug´, which is pharmacologically inactive. After oral administration, it is rapidly absorbed and converted to dabigatran in blood plasma and in the liver. Dabigatran is a potent, competitive, reversible, and direct thrombin-blocking agent.
Since thrombin enables the conversion of fibrinogen into fibrin during the coagulation formation, the blocking of thrombin by Dabigatran prevents the development of thrombus. Dabigatran blocks free thrombin, fibrin-bound thrombin and thrombin-induced coagulation formation.

How is Dabigatran etexilate DOC used?

The pharmaceutical form is hard capsule 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 Dabigatran etexilate DOC 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, Pradaxa. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Dabigatran etexilate DOC?

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 Dabigatran etexilate DOC approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Pradaxa, 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 Dabigatran etexilate DOC?"

What measures are being taken to ensure the safe and effective use of Dabigatran etexilate DOC?

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)
The educational material should contain a prescriber guide for HCP and a patient alert card for the patient as followed:

- Physician educational material:
  - The Summary of Product Characteristics
  - Guide for healthcare professionals (prescriber guide)

- The Prescriber Guide should contain the following key safety messages:
  - Details of populations potentially at higher risk of bleeding.
  - Information on medicinal products that are contraindicated, or which should be used with

caution due to an increased risk of bleeding and/or increased dabigatran exposure.
- Contraindication for patients with prosthetic heart valves requiring anticoagulant treatment.
- Recommendation for kidney function measurement.
- Recommendations for dose reduction in at risk populations.
- Management of overdose situations.
- The use of coagulation tests and their interpretation.
- That all patients should be provided with a Patient alert card and be counselled about:
  - Signs or symptoms of bleeding and when to seek attention from a health care provider.
  - Importance of treatment compliance.
  - Necessity to carry the Patient alert card with them at all times.
  - The need to inform Health Care Professionals about all medicines the patient is currently taking.
  - The need to inform Health Care Professionals that they are taking Dabigatran etexilate if they need to have any surgery or invasive procedure.
  - An instruction how to take Dabigatran etexilate.

- <u>The patient information pack:</u>
  - Patient information leaflet
  - Patient alert card

- <u>The Patient Alert Card should contain the following key safety messages:</u>
  - Signs or symptoms of bleeding and when to seek attention from a healthcare provider
  - Importance of treatment compliance
  - Necessity to carry the patient alert card with them at all times
  - The need to inform Health Care Professionals about all medicines they are currently taking
  - The need to inform Health Care Professionals that they are taking Dabigatran if they need to have any surgery or invasive procedure.

Other information about Dabigatran etexilate DOC

The full PAR for Dabigatran etexilate DOC can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Dabigatran etexilate DOC, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-10.