LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Dabigatran Etexilate Viatris (dabigatran etexilate mesilate)

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Summary Public Assessment Report

Dabigatran Etexilate Viatris
dabigatran etexilate mesilate

Capsule, hard, 75 mg, 110 mg, 150 mg

This is a summary of the public assessment report (PAR) for Dabigatran Etexilate Viatris. 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 Viatris 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.

75 mg
The product is used in adults to prevent the formation of blood clots in the veins after knee or hip replacement surgery.

The product is used in children to treat blood clots and to prevent blood clots from reoccurring.

110 mg
The product is used in adults to prevent the formation of blood clots in the veins after knee or hip replacement surgery; prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor; treat blood clots in the veins of your legs and lungs and to prevent blood clots from reoccurring in the vein of your legs and lungs.

The product is used in children to treat blood clots and to prevent blood clots from reoccurring.

150 mg
The product is used in adults to prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor; treat blood clots in the veins of your legs and lungs and to prevent blood clots from re-occurring in the vein of your legs and lungs.

The product is used in children to treat blood clots and to prevent blood clots from reoccurring.

How does Dabigatran Etexilate Viatris work?

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.

How is Dabigatran Etexilate Viatris 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 Viatris 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 Viatris?

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 Viatris 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 Pradaxa, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Dabigatran Etexilate Viatris?

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 for each therapeutic indication, targeting all physicians who are expected to prescribe/use dabigatran. This educational pack is aimed at increasing awareness about the potential risk of bleeding during treatment with dabigatran and providing guidance on how to manage that risk. The educational material should contain a prescriber guide for HCP and a patient alert card for the patient.

Other information about Dabigatran Etexilate Viatris

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

This summary was last updated in 2024-03.