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Dabigatran Etexilate Accord (*dabigatran etexilate*)

An overview of Dabigatran Etexilate Accord and why it is authorised in the EU

What is Dabigatran Etexilate Accord and what is it used for?

Dabigatran Etexilate Accord is an anticoagulant medicine used for:

- preventing the formation of blood clots in the veins in adults who have had an operation to replace a hip or knee;
- preventing stroke (caused by a blood clot in the brain) and systemic embolism (a blood clot in another organ) in adults who have an abnormal heartbeat called 'non-valvular atrial fibrillation' and are considered to be at risk of stroke;
- treating deep vein thrombosis (DVT, a blood clot in a deep vein, usually in the leg) and pulmonary embolism (PE, a clot in a blood vessel supplying the lungs) in adults, and preventing these conditions from occurring again.
- treating blood clots in veins and preventing them from occurring again in children.

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

Dabigatran Etexilate Accord contains the active substance dabigatran etexilate.

How is Dabigatran Etexilate Accord used?

Dabigatran Etexilate Accord is available as capsules for adults and children above 8 years of age. The medicine is to be taken by the mouth once or twice a day, and the duration of treatment and the dose depend on the condition the medicine is being used to treat or prevent and other medicines the patient is taking.

In all patients, kidney function should be assessed before starting treatment to exclude patients with severely reduced kidney function, and should be re-assessed during treatment if any worsening is suspected. When Dabigatran Etexilate Accord is used long term in patients with non-valvular atrial fibrillation, or when it is used in patients with DVT or PE, kidney function should be assessed at least once a year if their kidney function is mildly to moderately reduced or if they are over 75 years old.

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The medicine can only be obtained with a prescription.

For more information about using Dabigatran Etexilate Accord, see the package leaflet or contact your doctor or pharmacist.

How does Dabigatran Etexilate Accord work?

The active substance in Dabigatran Etexilate Accord, dabigatran etexilate, is a 'prodrug' of dabigatran. This means that it is converted into dabigatran in the body. Dabigatran is an anticoagulant, meaning that it prevents the blood from coagulating (clotting). It blocks a substance called thrombin, which is central to the process of blood clotting.

How has Dabigatran Etexilate Accord 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, Pradaxa, and do not need to be repeated for Dabigatran Etexilate Accord.

As for every medicine, the company provided studies on the quality of Dabigatran Etexilate Accord. The company also carried out a study 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 Dabigatran Etexilate Accord?

Because Dabigatran Etexilate Accord 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.

For the list of side effects and restrictions with Dabigatran Etexilate Accord, see the package leaflet.

Why is Dabigatran Etexilate Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dabigatran Etexilate Accord has been shown to have comparable quality and to be bioequivalent to Pradaxa. Therefore, the Agency's view was that, as for Pradaxa, the benefits of Dabigatran Etexilate Accord 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 Dabigatran Etexilate Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dabigatran Etexilate Accord have been included in the summary of product characteristics and the package leaflet.

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

Other information about Dabigatran Etexilate Accord

Dabigatran Etexilate Accord received a marketing authorisation valid throughout the EU on 26 May 2023.

Further information on Dabigatran Etexilate Accord can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/dabigatran-etexilate-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2023.