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Dabigatran etexilate Teva[1] (*dabigatran etexilate*)

An overview of Dabigatran etexilate Teva and why it is authorised in the EU

What is Dabigatran etexilate Teva and what is it used for?

Dabigatran etexilate Teva is an anticoagulant medicine (a medicine that prevents blood clotting) 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 blood clot in a blood vessel supplying the lungs) in adults, and preventing these conditions from occurring again;
- treating blood clots in veins in children and preventing them from occurring again.

Dabigatran etexilate Teva contains the active substance dabigatran etexilate.

Dabigatran etexilate Teva is a 'generic medicine'. This means that it 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 Teva is Pradaxa. For more information on generic medicines, see the question-and-answer document here.

How is Dabigatran etexilate Teva used?

Dabigatran etexilate Teva can only be obtained with a prescription. The medicine is taken by mouth and is available in different forms depending on the patient's age. The dose and duration of treatment depend on the condition the medicine is being used to treat, the patient's age and kidney function, and other medicines the patient is taking. For children the dose also depends on their weight.

All patients at increased risk of bleeding should be monitored closely and the doctor may reduce the dose of Dabigatran etexilate Teva.

[1] Previously known as Dabigatran etexilate Leon Farma

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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 Teva 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 in patients whose kidney function is mildly to moderately reduced or who are over 75 years old.

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

How does Dabigatran etexilate Teva work?

The active substance in Dabigatran etexilate Teva, 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 plays an important role in blood clotting.

How has Dabigatran etexilate Teva 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 Teva.

As for every medicine, the company provided studies on the quality of Dabigatran etexilate Teva. The company also carried out two studies 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 Teva?

Because Dabigatran etexilate Teva 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 Teva, see the package leaflet.

Why is Dabigatran etexilate Teva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Dabigatran etexilate Teva 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 Teva 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 Teva?

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

Any additional measures in place for Pradaxa, such as a patient card with key safety information, also apply to Dabigatran etexilate Teva where appropriate.

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

Other information about Dabigatran etexilate Teva

Dabigatran etexilate Leon Farma received a marketing authorisation valid throughout the EU on 19 February 2024.

The name of the medicine was changed to Dabigatran etexilate Teva on 19 August 2024.

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

This overview was last updated in 08-2024.