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Withdrawal of application for the marketing authorisation of Dabigatran etexilate Teva (dabigatran etexilate)

Teva GmBh withdrew its application for a marketing authorisation of Dabigatran etexilate Teva as an anticoagulant medicine (a medicine that prevents blood clotting).

The company withdrew the application on 13 June 2024.

What is Dabigatran etexilate Teva and what was it intended to be used for?

Dabigatran etexilate Teva is an anticoagulant medicine which was developed for:

- preventing the formation of blood clots in the veins of 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 Teva contains the active substance dabigatran etexilate. It was to be available as capsules for adults and children above 8 years of age from the time they are able to swallow soft food.

Dabigatran etexilate Teva was developed as a 'generic medicine'. This means that Dabigatran etexilate Teva contained the same active substance as an authorised 'reference medicine' called Pradaxa and was intended to work in the same way. For more information on generic medicines, see the question-and-answer document here.

How does Dabigatran etexilate Teva work?

The active substance in this medicine, 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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What did the company present to support its application?

Studies on the benefits and risks of the active substance are not needed for a generic medicine because they have already been carried out with the reference medicine. As for every medicine, the company provided studies on the quality of Dabigatran etexilate Teva. The company also provided studies to investigate whether Dabigatran etexilate Teva is 'bioequivalent' to the reference medicine Pradaxa. 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.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response the Agency's questions, at the time of the withdrawal, concerns remained on the presence of nitrosamine impurities in the medicine and its provisional opinion was that Dabigatran etexilate Teva could not have been authorised for the requested indication.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Dabigatran etexilate Teva did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that its withdrawal was based on commercial reasons.