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Apixaban Accord (*apixaban*)

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

What is Apixaban Accord and what is it used for?

Apixaban Accord is a medicine used to prevent venous thromboembolism (blood clots in the veins) in adults following a hip or knee replacement operation. It is also used in adults to treat deep vein thrombosis (blood clot in a deep vein, usually in the leg) and pulmonary embolism (clot in a blood vessel supplying the lungs), and to prevent their reoccurrence.

Additionally, Apixaban Accord is used to prevent stroke (caused by blood clots in the brain) and blood clots in other organs in adults with atrial fibrillation (irregular rapid contractions of the upper chambers of the heart). It is used in patients who have one or more risk factors, such as having had a previous stroke, having high blood pressure, diabetes, heart failure or being 75 years old or over.

Apixaban Accord contains the active substance apixaban.

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

How is Apixaban Accord used?

Apixaban Accord can only be obtained with a prescription. It is available as tablets to be taken by mouth.

The dose and duration of treatment depends on the condition the medicine is being used to treat or prevent; for patients with atrial fibrillation, the dose depends on age, bodyweight and level of creatinine in the blood.

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

How does Apixaban Accord work?

Patients undergoing hip or knee replacement surgery, who have had a recent trauma, or are confined to bed are at a high risk of blood clots forming in the veins, which can be dangerous and even fatal if these clots move to another part of the body such as the lungs. Similarly, patients with atrial

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fibrillation are at high risk of clots forming in the heart, which can reach the brain where they can cause a stroke.

The active substance in Apixaban Accord, apixaban, is a 'factor Xa inhibitor'. This means that it blocks factor Xa, an enzyme that is involved in the production of thrombin. Thrombin is central to the process of blood clotting. By blocking factor Xa, apixaban reduces the levels of thrombin in the blood, which reduces the risk of blood clots forming in the arteries and veins.

How has Apixaban 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, Eliquis, and do not need to be repeated for Apixaban Accord.

As for every medicine, the company provided studies on the quality of Apixaban 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 Apixaban Accord?

Because Apixaban 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.

Why is Apixaban Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Apixaban Accord has been shown to be comparable to Eliquis. Therefore, the Agency's view was that, as for Eliquis, the benefits of Apixaban 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 Apixaban Accord?

The company that markets Apixaban Accord will provide educational material for healthcare professionals expected to prescribe Apixaban Accord that addresses the risk of bleeding during treatment.

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

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

Other information about Apixaban Accord

Apixaban Accord received a marketing authorisation valid throughout the EU on 23 July 2020.

Further information on Apixaban Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/apixaban-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 07-2020.