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EPAR summary for the public

Roteas

edoxaban

This is a summary of the European public assessment report (EPAR) for Roteas. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Roteas.

For practical information about using Roteas, patients should read the package leaflet or contact their doctor or pharmacist.

What is Roteas and what is it used for?

Roteas is an anticoagulant medicine (a medicine that prevents blood clotting) used in adults:

- to prevent stroke (caused by blood clots in the brain) and systemic embolism (blood clots in other organs) in patients with non-valvular 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, high blood pressure, diabetes, heart failure or being 75 years old or over;
- to treat deep-vein thrombosis (DVT, a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent DVT and pulmonary embolism from re-occurring.

Roteas contains the active substance edoxaban.

This medicine is the same as Lixiana, which is already authorised in the European Union (EU). The company that makes Lixiana has agreed that its scientific data can be used for Roteas ('informed consent').

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How is Roteas used?

Roteas is available as tablets (15, 30 and 60 mg) and can only be obtained with a prescription. The usual dose is 60 mg once a day. Treatment is continued while the benefit outweighs the risk of bleeding, which depends on the condition being treated and any existing risk factors. Doses should be halved in patients with moderately or severely reduced kidney function, or low body weight or in those who are also taking certain medicines (known as P-gp inhibitors) that can interfere with the removal of edoxaban from the body. Dose adjustments may also need to be made in patients who are switched between Roteas and other anticoagulant medicines. For further information, see the package leaflet.

How does Roteas work?

The active substance in Roteas, edoxaban, is a 'factor Xa inhibitor'. This means that it blocks factor Xa, an enzyme that is involved in the production of thrombin. Thrombin is essential for blood clotting. By blocking factor Xa, the medicine reduces the levels of thrombin in the blood, which helps treat clots and reduce the risk of them forming in the arteries and veins and leading to DVT, pulmonary embolism, stroke or other organ damage.

What benefits of Roteas have been shown in studies?

Roteas has been shown to be as effective as the standard anticoagulant warfarin in preventing stroke and systemic embolism in patients with atrial fibrillation. The effects were studied in one main study, which involved over 21,000 patients for an average of 2.5 years. The main measure of effectiveness was the rate of stroke or systemic embolism among the patients each year. A first systemic embolism or stroke occurred in 182 patients given standard doses of Roteas and in 232 of those given warfarin, corresponding to annual rates for these events of around 1.2% and 1.5% respectively. When another recommended definition of the type of stroke was used, embolism or stroke due to blood clots was seen in 143 patients given Roteas (0.9%) and 157 given warfarin (1%). There was a trend for better results in patients with reduced kidney function than those whose kidney function was normal.

In the treatment and prevention of blood clots in patients with DVT or pulmonary embolism, Roteas was also found to be as effective as warfarin, in a study involving over 8,200 patients. The main measure of effectiveness was the number of patients who had another episode of DVT or pulmonary embolism during the study period. Further episodes were seen in 130 of 4,118 patients given edoxaban (3.2%) and in 146 of 4,122 given warfarin (3.5%).

What are the risks associated with Roteas?

The most common side effects with Roteas (which may affect up to 1 in 10 people) are bleeding from skin and soft tissues, nose (epistaxis) and the vagina. Bleeding can occur at any site and can be severe or even fatal. Other common side effects are anaemia (low levels of red blood cells), rash and abnormal results in tests of liver function. For the full list of all side effects reported with Roteas, see the package leaflet.

Roteas must not be used in patients who are actively bleeding, have liver diseases that affect blood clotting, have severe uncontrolled high blood pressure or who have a condition putting them at significant risk of major bleeding. It must also not be used in pregnant or breastfeeding women or together with another anticoagulant. For the full list of restrictions, see the package leaflet.

Why is Roteas approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Roteas's benefits are greater than its risks and recommended that it be approved for use in the EU. The medicine has been shown to be at least as effective as warfarin in reducing stroke rates in patients with atrial fibrillation and in preventing further episodes of DVT or pulmonary embolism.

With respect to safety, overall the risk of serious bleeding such as bleeding into the brain was reduced compared with warfarin, although there may be less difference where warfarin treatment is well managed. Although there was greater a risk of bleeding from the mucosa (tissues lining body cavities such as the nose, gut and vagina), the Committee considered that the risk could be managed with appropriate measures.

What measures are being taken to ensure the safe and effective use of Roteas?

The company that markets Roteas will provide educational materials for doctors prescribing the medicine and an alert card for patients, explaining the risks of bleeding with the medicine and how to manage them. It will also carry out a study of the effects of the medicine in patients with atrial fibrillation and good kidney function.

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

Other information about Roteas

The European Commission granted a marketing authorisation valid throughout the European Union for Roteas on 20. April 2017

The full EPAR for Roteas can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Roteas, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2017.