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EPAR summary for the public

Tacforius

tacrolimus

This is a summary of the European public assessment report (EPAR) for Tacforius. 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 Tacforius.

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

What is Tacforius and what is it used for?

Tacforius is used for the long-term treatment of adult patients who have had a kidney or liver transplant, to prevent rejection (when the immune system attacks the transplanted organ). Tacforius can also be used to treat organ rejection in adult patients when other immunosuppressive medicines (medicines that reduce the activity of the immune system) are not effective.

Tacforius contains the active substance tacrolimus and is a 'generic medicine'. This means that Tacforius contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Advagraf. For more information on generic medicines, see the question-and-answer document here.

How is Tacforius used?

Tacforius is available as prolonged-release capsules containing tacrolimus. The prolonged-release capsules allow tacrolimus to be released slowly from the capsule over several hours so that it needs to be taken only once a day.

Doses of Tacforius are calculated on the basis of the patient's weight and the type of transplant the patient has had. Starting doses are between 0.1 and 0.3 mg per kg bodyweight daily. The doses are

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then adjusted according to the patient's response and the medicine's blood levels. Tacforius should be taken once daily with water, on an empty stomach. For further information, see the package leaflet.

Tacforius can only be obtained with a prescription. Only doctors experienced in immunosuppressive medicines and in the management of transplant patients should prescribe it and make changes to immunosuppressive treatment.

How does Tacforius work?

Tacrolimus, the active substance in Tacforius, is an immunosuppressive medicine. Tacrolimus reduces the activity of cells in the immune system, called T-cells, that are primarily involved in attacking the transplanted organ (organ rejection).

How has Tacforius been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Advagraf, and do not need to be repeated for Tacforius.

As for every medicine, the company provided studies on the quality of Tacforius. The company also carried out 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 Tacforius?

Because Tacforius 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 Tacforius approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Tacforius has been shown to have comparable quality and to be bioequivalent to Advagraf. Therefore, the Agency's view was that, as for Advagraf, the benefit outweighs the identified risk. The Agency recommended that Tacforius be approved for use in the EU.

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

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

Other information about Tacforius

The European Commission granted a marketing authorisation valid throughout the European Union for Tacforius on 8 December 2017.

The full EPAR for Tacforius 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 Tacforius, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 12-2017.