LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Certican
(everolimus)

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Summary Public Assessment Report

Certican
(everolimus)

Tablet, 0.25 mg, 0.5 mg, 0.75 mg, 1.0 mg
Dispersible tablet, 0.1 mg, 0.25 mg

This is a summary of the public assessment report (PAR) for Certican. It explains how Certican was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Certican.

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

What is Certican and what is it used for?

Certican is used in the treatment of

Kidney and heart transplantation
Certican is indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and corticosteroids.

Liver transplantation
Certican is indicated for the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Certican should be used in combination with tacrolimus and corticosteroids.

How does Certican work?

The active substance of Certican is everolimus.

Everolimus belongs to a group of medicines called immunosuppressants. It is used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver.
Certican is used together with other medicines, such as ciclosporin for kidney and heart transplantation, tacrolimus for liver transplantation, and corticosteroids.

How is Certican used?

The pharmaceutical form of Certican is tablets and dispersible tablets for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Certican have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Certican effectively prevents graft rejection in patients undergoing renal, liver and heart transplantation.

What are the possible side effects of Certican?

For the full list of all side effects reported with Certican, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Certican approved?

It was noted that the effect of Certican in the treatment of graft rejection in patients undergoing renal, liver and heart transplantation was at least as effective as the comparator product. Therefore, the Medical Products Agency in Sweden decided that Certican's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Certican is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Certican, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Certican

The marketing authorisation for Certican was granted on 2003-07-18 in Sweden.

The full PAR for Certican can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Certican, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2014-11-18.