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Advagraf (*tacrolimus*)

A plain-language overview of Advagraf and why it is authorised in the EU

What is Advagraf and what is it used for?

Advagraf is a medicine used in adults who have had a kidney or liver transplant, to prevent rejection (when the immune system, the body's natural defences, attacks the transplanted organ). Advagraf can also be used to treat organ rejection in adults when other immunosuppressive medicines (medicines that reduce the activity of the immune system) are not effective.

Advagraf contains the active substance tacrolimus.

How is Advagraf used?

Advagraf is available as prolonged-release capsules, which slowly release tacrolimus over several hours. It is taken once a day in the morning, on an empty stomach or at least 1 hour before or 2 to 3 hours after food. The dose of Advagraf is calculated based on the patient's weight, the type of transplant and whether it's used to prevent the rejection of the new organ or to treat it. The dose is adjusted according to the patient's response and the level of medicine in the blood.

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

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

How does Advagraf work?

The active substance in Advagraf, tacrolimus, is an immunosuppressant. It reduces the activity of cells in the immune system, called T-cells, that are primarily involved in attacking the transplanted organ (organ rejection).

What benefits of Advagraf have been shown in studies?

Tacrolimus has been used since the mid-1990s. In the EU, it was first available as capsules under the name Prograf or Prograft (depending on the country). The company presented the results of studies

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

that were previously carried out with Prograf/Prograft, as well as information from the published literature.

It also presented the results of a clinical study in 668 kidney transplant patients comparing the use of Advagraf with that of Prograf/Prograft or ciclosporin (another immunosuppressive medicine used to prevent rejection). All of the patients were also given the immunosuppressive medicine mycophenolate mofetil. The main measure of effectiveness was the number of patients in whom the transplant failed (as measured by looking at, for example, the need for a repeat transplant or a return to dialysis) after one year's treatment. Advagraf was as effective as both comparator medicines. After one year, 14% of the patients receiving Advagraf had experienced organ failure (30 out of 214), compared with 15% in the patients treated with Prograf/Prograft (32 out of 212) and 17% in those treated with ciclosporin (36 out of 212).

Further shorter studies were also carried out in 119 kidney transplant patients and 129 liver transplant patients, looking at how Advagraf taken once a day is absorbed by the body in comparison with Prograf/Prograft taken twice a day. These studies showed that Advagraf and Prograf/Prograft produce similar levels of tacrolimus in the body.

Studies carried out with Advagraf are described in more detail in the medicine's assessment reports.

What are the side effects and restrictions with Advagraf?

For the full list of side effects and restrictions with Advagraf, see the package leaflet.

The most common side effects with Advagraf (which may affect more than 1 in 10 people) include tremor (shaking), renal impairment (kidney problems), hyperglycaemia (high blood glucose levels), diabetes, hyperkalaemia (high blood potassium levels), infections, hypertension (high blood pressure) and insomnia (difficulty sleeping).

Advagraf must not be used in people who are hypersensitive (allergic) to macrolide antibiotics (such as erythromycin).

Why is Advagraf authorised in the EU?

The European Medicines Agency decided that Advagraf's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Advagraf

Advagraf received a marketing authorisation valid throughout the EU on 23 April 2007.

Further information on Advagraf, including the product information and the assessment reports, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/advagraf.

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