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EPAR summary for the public

Nulojix

belatacept

This is a summary of the European public assessment report (EPAR) for Nulojix. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Nulojix.

What is Nulojix?

Nulojix is a powder that is made up into a solution for infusion (drip into a vein). It contains the active substance belatacept.

What is Nulojix used for?

Nulojix is used in adults to prevent the body from rejecting a transplanted kidney.

It is used with corticosteroids and a mycophenolic acid (other medicines used to prevent organ rejection). An interleukin-2 receptor antagonist medicine should also be used with Nulojix during the first week after the kidney transplant.

The medicine can only be obtained with a prescription.

How is Nulojix used?

Nulojix should only be prescribed and supervised by a doctor who has experience in the management of kidney transplant patients.

Nulojix is given as an infusion into a vein over 30 minutes. Doses are calculated using the patient's weight. In the initial phase it is given at a dose of 10 mg per kilogram body weight on day 1 (day of transplantation or the day before) and then again on days 5, 14 and 28. Further doses are given at the end of weeks 8 and 12.

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After the initial phase, which lasts three months, Nulojix is given at a maintenance dose of 5 mg/kg every four weeks starting from the end of the week 16.

How does Nulojix work?

The active substance in Nulojix, belatacept, is an immunosuppressive medicine. It suppresses the activity of 'T cells', immune system cells that can become involved in organ rejection.

T cells must be 'activated' before they work. This happens when certain molecules attach to receptors on the surface of the T cells. Belatacept has been designed to attach to two of these molecules called CD80 and CD86. This stops them activating the T cells, helping to prevent organ rejection.

How has Nulojix been studied?

In two main studies involving 1,209 patients who underwent a kidney transplant, Nulojix was compared with cyclosporine A (another medicine used to prevent organ rejection). Some patients were given intensive Nulojix treatment which involved a longer initial phase of six months. All patients were also treated with corticosteroids, mycophenolic acid, and basiliximab (an interleukin-2 receptor antagonist) during the first week after transplantation.

The main measures of effectiveness were the proportion of patients who survived with their transplanted kidneys intact and how well their kidneys functioned. The studies also looked at the number of organ rejections that occurred within one year of the transplant.

What benefit has Nulojix shown during the studies?

Nulojix was shown to improve patient and organ survival following kidney transplantation. In the first study, 97% of patients receiving Nulojix treatment survived with their kidneys intact (218 out of 226) compared with 93% of patients receiving cyclosporine A (206 out 221). Around 54% of patients receiving Nulojix and 78% of those receiving cyclosporine A had impaired kidney function. The proportion of patients who had an episode of organ rejection within one year was 17% for Nulojix and 7% for cyclosporine A.

In the second study, 89% (155 out of 175) of patients on Nulojix and 85% (157 out 184) of those on cyclosporine A survived with their kidneys intact. The proportion of patients with impaired kidney function was 77% in patients on Nulojix and 85% in patients on cyclosporine A. Around 18% of patients on Nulojix had an episode of organ rejection within one year compared with 14% of patients on cyclosporine A.

Intensive Nulojix treatment with a longer initial phase of six months produced similar results to treatment with a three-month initial phase.

What is the risk associated with Nulojix?

The most common serious side effects of Nulojix seen in more than 2% of patients are: urinary tract infection (infection of the structures that carry urine), cytomegalovirus infection, pyrexia (fever), increased blood creatinine (a marker of kidney problems), pyelonephritis (kidney infection), diarrhoea, gastroenteritis (diarrhoea and vomiting), poor functioning of the transplanted kidney, leucopenia (low white blood cell counts), pneumonia (infection of the lungs), basal cell carcinoma (a cancer), anaemia (low red blood cell counts), dehydration. For the full list of all side effects reported with Nulojix, see the package leaflet.

Nulojix must not be used in patients who have not been exposed to the Epstein-Barr virus or in whom previous exposure is uncertain. This is because patients treated with Nulojix who have had no previous exposure to the virus are at higher risk of getting a type of cancer known as post-transplant lymphoproliferative disorder. For the full list of restrictions, see the package leaflet.

Why has Nulojix been approved?

The CHMP noted that Nulojix does not have the toxic effects on the kidneys seen with other immunosuppressive medicines commonly used in transplantation. Although the studies showed more acute rejections after one year of treatment with Nulojix compared with cyclosporine A, this did not lead to reduced patient and organ survival after three years. Overall, the benefits of Nulojix compared well with the comparator medicine. The CHMP therefore concluded that Nulojix's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Nulojix 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 Nulojix, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes Nulojix will include an alert card in each medicine's pack to increase awareness of the benefits and risks with Nulojix.

Other information about Nulojix

The European Commission granted a marketing authorisation valid throughout the European Union for Nulojix on 17 June 2011.

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

This summary was last updated in 02-2016.