EMA/252902/2021
EMEA/H/C/002098

Nulojix (*belatacept*)

An overview of Nulojix and why it is authorised in the EU

What is Nulojix and what is it used for?

Nulojix is a medicine that reduces the activity of the immune system (the body's natural defences) and is used in adults to prevent the body from rejecting a transplanted kidney. It contains the active substance belatacept.

How is Nulojix used?

Nulojix can only be obtained with a prescription. Treatment should be supervised by a doctor who has experience in the management of kidney transplant patients.

Nulojix is given as an infusion (drip) into a vein over 30 minutes. It can be used in transplant patients from the day of transplantation and then regularly as maintenance treatment. When Nulojix is used this way, the patient also receives treatment with basiliximab, corticosteroids and mycophenolic acid (other medicines used to prevent organ rejection).

Nulojix is also used for maintenance treatment in patients who received kidney transplantation at least 6 months earlier and who had been using a calcineurin inhibitor-based regimen (another type of immunosuppressive treatment). Calcineurin inhibitor treatment can then be progressively replaced with Nulojix.

The doses and frequency depend on the context in which Nulojix is used. For more further information about using Nulojix, see the package leaflet or contact your doctor or pharmacist.

How does Nulojix work?

The active substance in Nulojix, belatacept, is an immunosuppressant 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.

What benefits of Nulojix have been shown in studies?

Nulojix was shown to improve patient and organ survival following kidney transplantation.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

In two main studies involving 1,209 patients who had just had a transplant, Nulojix was compared with ciclosporin (another medicine used to prevent organ rejection). All patients were also treated with corticosteroids, mycophenolic acid and basiliximab (an interleukin-2 receptor antagonist) during the first week after 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 ciclosporin (206 out 221). Around 54% of patients receiving Nulojix and 78% of those receiving ciclosporin 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 ciclosporin survived with their kidneys intact. The proportion of patients with impaired kidney function was 77% in patients on Nulojix and 85% in patients on ciclosporin. Around 18% of patients on Nulojix had an episode of organ rejection within one year compared with 14% of patients on ciclosporin.

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

In a further study in 446 patients who underwent kidney transplantation more than 6 months earlier and were being treated with a calcineurin inhibitor (ciclosporin or tacrolimus), half of the patients continued on calcineurin inhibitor treatment and the other half were progressively switched to Nulojix over 4 weeks. After 2 years, 98% of patients (219 out of 223) who were switched to Nulojix were alive with a working transplanted kidney, compared with 97% (217 out of 223) of patients who were not switched.

What are the risks associated with Nulojix?

The most common serious side effects with Nulojix (which can affect more than 2 in 100 people) 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 type of skin cancer), anaemia (low red blood cell counts), dehydration. For the full list of side effects of 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 is Nulojix authorised in the EU?

The European Medicines Agency noted that Nulojix does not have the toxic effects on the kidneys seen with some immunosuppressant medicines commonly used in transplantation. Although the studies showed more acute rejections after one year of treatment with Nulojix compared with ciclosporin, this did not lead to reduced patient and organ survival after three years. Overall, the benefits of Nulojix compared well with those of the comparator medicine.

Nulojix is also effective at preventing rejection in patients who had been using calcineurin inhibitor treatment and have been switched to Nulojix at least 6 months after transplantation.

The Agency decided that Nulojix'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 Nulojix?

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

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

Other information about Nulojix

Nulojix received a marketing authorisation valid throughout the EU on 17 June 2011.

Further information on Nulojix can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Nulojix.

This overview was last updated in 05-2021.