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Idefirix (*imlifidase*)

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

What is Idefirix and what is it used for?

Idefirix is a medicine used to prevent the body from rejecting a newly transplanted kidney.

Idefirix is used before transplantation in adults who have antibodies against the donor kidney and are considered 'highly sensitised' based on a positive crossmatch test. It should be reserved for patients who are unlikely to obtain a transplant under the available kidney allocation system.

Graft organ rejection following solid organ transplantation is rare, and Idefirix was designated an 'orphan medicine' (a medicine used in rare diseases) on 12 January 2017. Further information on the orphan designation can be found here: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3161826.

Idefirix contains the active substance imlifidase.

How is Idefirix used?

Idefirix is for hospital use only and can only be obtained with a prescription. Idefirix treatment should only be prescribed and supervised by a doctor experienced in the use of immunosuppressive medicines (medicines that reduce the activity of the immune system, the body's natural defences) and in the management of sensitised kidney transplant patients.

Idefirix is given as an infusion (drip) into a vein. The medicine is given as a single dose in the 24 hours before transplantation. If necessary, a second dose can be given within 24 hours after the first dose.

Patients treated with Idefirix still require standard immunosuppressive therapy after kidney transplantation.

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

How does Idefirix work?

Highly sensitised patients have high levels of antibodies (proteins in the blood that fight infections and other foreign cells) against the donor's tissue, including immunoglobulin G (IgG) antibodies. This makes their body more likely to reject the donor organ. The active substance in Idefirix, imlifidase, is

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an enzyme (a protein) that breaks down the IgG antibodies, thereby reducing the likelihood of the body rejecting the donor kidney.

What benefits of Idefirix have been shown in studies?

Idefirix was investigated in one main study of 19 patients with end-stage kidney disease who were highly sensitised to the donor kidney based on a positive crossmatch test. Within 24 hours of receiving Idefirix, 17 of the patients became crossmatch-negative and one was borderline crossmatch-positive, making all 18 eligible for kidney transplantation. A total of 16 patients had a functioning kidney 6 months after transplantation.

Additional data on the benefits of Idefirix came from three supportive studies. Analyses of the data from all four studies showed that 43 out of a total of 46 patients had a functioning kidney 6 months after transplantation.

What are the risks associated with Idefirix?

The most common side effects with Idefirix (which may affect more than 1 in 10 people) are infections, including pneumonia (infection of the lungs), urinary tract infection and sepsis (blood poisoning). Other common side effects (which may affect up to 1 in 10 people) are pain and reactions around the infusion site, increased blood levels of certain liver enzymes, muscle pain, headache and flushing.

The most common serious side effects with Idefirix (which may affect up to 1 in 10 people) are pneumonia and sepsis.

Idefirix should not be used in people with a serious infection or thrombotic thrombocytopenic purpura.

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

Why is Idefirix authorised in the EU?

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

Antibodies against the donor's graft are a major obstacle to successful transplantation in patients with kidney failure. Patients who are highly sensitised therefore usually remain on dialysis with shorter life expectancy and poor quality of life. In light of this unmet medical need and despite the need for further data, the Agency considered that the available evidence suggests that Idefirix is effective at reducing antibody levels in highly sensitised adults, allowing them to receive a kidney transplant. The safety profile of Idefirix is considered manageable.

Idefirix has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Idefirix?

Since Idefirix has been given conditional authorisation, the company that markets Idefirix will provide additional data from an ongoing study into the long-term graft functioning and survival in patients who have undergone kidney transplantation after Idefirix treatment. The company will also provide data from a new study to confirm the long-term effectiveness and safety of Idefirix.

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

The company that markets Idefirix will provide results of a long-term study of Idefirix to confirm its effectiveness.

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

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

Other information about Idefirix

Idefirix received a conditional marketing authorisation valid throughout the EU on 25 August 2020.

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

This overview was last updated in 08-2020.