swissmedic

Public Summary SwissPAR dated 6 October 2022

Idefirix® (active substance: imlifidase)

Temporary authorisation in Switzerland: 6 May 2022

Concentrate for solution for infusion for temporary inactivation of immunoglobulin G in kidney transplantations

About the medicine

The medicinal product Idefirix, containing the active substance imlifidase, is used in adult kidney transplant patients who have a positive crossmatch test against the available donor organ. In the event of a positive crossmatch, the organ recipient is not compatible with the kidney donor because their immune system has developed antibodies (a type of protein) that react against organs and cells from the donor and will lead to the transplanted organ being rejected. The use of Idefirix is reserved for patients who are unlikely to receive a transplantation under the donor kidney allocation system, including prioritisation programmes for highly sensitised patients.

Mode of action

The active substance imlifidase is an enzyme that breaks down immunoglobulin G (IgG). IgGs (a type of antibody) are formed by the immune system to defend against foreign substances.

A crossmatch test is carried out before an organ transplantation to test compatibility. A positive crossmatch test means that the organ recipient has antibodies against the donor organ. The patient is "sensitised" and the body would reject the donor organ. Administration of Idefirix temporarily makes the donor recipient's IgG ineffective. The crossmatch test performed subsequently is negative. This reduces the risk of the transplanted organ being rejected due to an antibody reaction.

Use

Idefirix, containing the active substance imlifidase, is a prescription-only medicine. Idefirix is available as a concentrate for solution for infusion. The recommended dose is a single administration of 0.25 mg per kilogram of body weight. The infusion is given preferably in the 24 hours before the transplantation and is administered into a vein over 15 minutes. A further crossmatch test should

then be carried out before the transplantation to confirm the change in result from positive to negative.

Efficacy

The efficacy of Idefirix was investigated in three studies in a total of 54 patients with end-stage renal disease, of whom 46 needed to undergo a kidney transplantation. All patients who had a positive crossmatch test before the transplantation had a negative test result following treatment with Idefirix. Six months after the transplantation, all 46 patients were alive, although the transplanted organ was no longer functioning in three cases. Long-term data regarding the risk of a later organ rejection are not yet available.

Precautions, undesirable effects & risks

Idefirix must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common (in 15 out of 100 people) adverse reactions are infections, including pneumonia (5.6%), cystitis (5.6%) and sepsis (blood poisoning, 3.7%).

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The medicinal product Idefirix was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Idefirix, the Information for healthcare professionals was not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch.
Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.