Package leaflet: Information for the user

Idefirix 11 mg powder for concentrate for solution for infusion
imlifidase

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Idefirix is and what it is used for
2. What you need to know before you are given Idefirix
3. How to use Idefirix
4. Possible side effects
5. How to store Idefirix
6. Contents of the pack and other information

1. What Idefirix is and what it is used for

Idefirix contains the active substance imlifidase, which belongs to a group of medicines called immunosuppressants. It is given before your kidney transplantation to prevent the immune system (your body's defences) from rejecting the donated kidney.

Idefirix works by breaking down a type of antibody in the body called immunoglobulin G (IgG), which is involved in destroying 'foreign' or harmful substances.

Imlifidase is a protein from a bacterium called *Streptococcus pyogenes*.

2. What you need to know before you are given Idefirix

You must not be given Idefirix
- If you are allergic to imlifidase or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe infection.
- If you have a blood disorder called thrombotic thrombocytopenic purpura (TTP), that results in blood clots forming in small blood vessels throughout the body.

Warnings and precautions

Infusion reactions
Idefirix contains a protein and it can cause allergic reactions in some people. You will receive medicines to reduce the risk of an allergic reaction. If you get any symptoms of an allergic reaction, such as severe rash, shortness of breath, feeling hot, flushing, during the infusion (‘drip’), the infusion may need to be slowed down or stopped. When these symptoms go away, or improve, the infusion can be continued.

Infections
IgG is important for protecting you against infections and since Idefirix breaks down IgG, you will receive antibiotics to reduce the risk of infections.

Antibody-mediated rejection (AMR)
Your body will produce new IgG antibodies, which may attack the transplanted kidney. Your doctor will monitor you closely and you will receive medicines to reduce the risk of rejection.

Children and adolescents
Do not give this medicine to children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and Idefirix
Tell your doctor if you are using, have recently used or might use any other medicines. Idefirix can affect the way some medicines work, and the dose of these may have to be adjusted.

As Idefirix breaks down IgG, IgG-based medicines may not work if given at the same time as Idefirix. This includes the following medicines:
- basiliximab (used to prevent rejection of kidney transplants)
- rituximab (used to treat cancers such as non-Hodgkin's lymphoma and chronic lymphocytic leukaemia and inflammatory diseases such as rheumatoid arthritis)
- alemtuzumab (used to treat a form of multiple sclerosis)
- adalimumab (used to treat inflammatory diseases such as rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease and ulcerative colitis)
- denosumab (used to treat osteoporosis)
- belatacept (used to prevent rejection of kidney transplants)
- etanercept (used to treat inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis)
- rabbit anti-thymocyte globulin (rATG) (used to prevent rejection of kidney transplants)
- intravenous immunoglobulin (IVIg) (used to increase abnormally low immunoglobulin levels in the blood or to treat inflammatory diseases such as Guillain-Barré syndrome, Kawasaki disease and chronic inflammatory demyelinating polyneuropathy).

Pregnancy and breast-feeding
Idefirix is not recommended during pregnancy.
Talk to your doctor if you think you may be pregnant.

It is not known whether Idefirix passes into breast milk. You should not breast-feed if you are being treated with Idefirix.

Idefirix contains sodium and polysorbate 80
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ′sodium-free′.

This medicine contains 0.5 mg of polysorbate 80 in each ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Idefirix

Idefirix will be prescribed by a doctor with experience in kidney transplantation and it is for use in a hospital. The medicine will be given by infusion into your vein over about 15 minutes.

A healthcare professional will calculate the right dose for you based on your weight. Idefirix is usually given as a single dose, but your doctor may decide to give a second dose before the transplantation.

Information for healthcare professionals on dose calculation, preparation and infusion of Idefirix is given at the end of this leaflet.

If you receive more Idefirix than you should
During and after the infusion you will be closely monitored. Healthcare professionals will check for any side effects.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following:
- Signs of infection, such as fever, chills, cough, feeling weak or generally unwell (very common - may affect more than 1 in 10 people).
- Signs of an infusion reaction, such as severe rash, shortness of breath, feeling hot, flushing (common - may affect up to 1 in 10 people).
- Muscle pain or fatigue (symptoms of myalgia) (common - may affect up to 1 in 10 people).

Other side effects include:

Common (may affect up to 1 in 10 people):
- Infections: lung infection (pneumonia), infections of the blood (sepsis), abdominal infection, upper respiratory tract infection, adenovirus infection, parvovirus infection, urinary tract infection, influenza, wound infection, post-operative wound infection, catheter site infection
- Transplant rejection (IgG antibodies will try to reject your donor kidney and you can feel general discomfort)
- High or low blood pressure (symptoms of low blood pressure can be dizziness and symptoms of high blood pressure can be headache)
- Low number of red blood cells (anaemia)
- Dizziness at change of body position, e.g. when standing up
- Headache
- Burst blood vessel in the eye
- Decreased vision
- Increased heart rate
- Infusion site pain
- Increased liver enzymes (seen in blood tests)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Idefirix

Keep this medicine out of the sight and reach of children. Idefirix is stored in the hospital pharmacy.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2-8°C). Do not freeze. Store in the original package in order to protect from light.

Chemical and physical in-use stability after reconstitution and dilution has been demonstrated for 24 hours at 2-8°C including 4 hours at 25°C during this 24-hour period.

Do not use this medicine if you notice particulate matter or discolouration after reconstitution.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Idefirix contains
- The active substance is imlifidase. Each vial contains 11 mg imlifidase. After reconstitution, each mL of concentrate contains 10 mg imlifidase.
- The other ingredients are mannitol, polysorbate 80, trometamol, disodium edetate dihydrate and hydrochloric acid (for pH adjustment). See section 2 “Idefirix contains sodium and polysorbate 80”.

What Idefirix looks like and contents of the pack
- Idefirix is supplied as a glass vial containing a powder for concentrate for solution for infusion (powder for concentrate). The powder is a white freeze-dried cake.
- Packs contain 1 or 2 vials. Not all pack sizes may be marketed.

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This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
New information on this medicinal product will be reviewed at least every year and this leaflet will be updated as necessary.

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

Reconstitution of powder
Introduce 1.2 mL of sterile water for injections into the Idefirix vial, taking care to direct the water to the glass wall and not into the powder.

Swirl the vial gently for at least 30 seconds to dissolve the powder completely. Do not shake so as to minimise the likelihood of forming foam. The vial will now contain imlifidase 10 mg/mL and up to 1.1 mL of the solution can be withdrawn.

The reconstituted solution should be clear to slightly opalescent and colourless or slightly yellow. Do not use if particles are present or the solution is discoloured. It is recommended to transfer the reconstituted solution from the vial to the infusion bag immediately.

Preparation of the solution for infusion
Slowly add the correct amount of reconstituted imlifidase solution to an infusion bag containing 50 mL of sodium chloride 9 mg/mL (0.9%) solution for infusion. Invert the infusion bag several times to thoroughly mix the solution. The infusion bag should be protected from light at all times.

Prior to use the solution for infusion should be inspected visually for particulate matter or discolouration. Discard the solution if any particulate matter or discolouration is observed.

Administration
The entire, fully diluted infusion should be infused over 15 minutes through an infusion set and a sterile, inline, non-pyrogenic, low protein-binding filter (pore size of 0.2 μm). At the end of the infusion, flushing the intravenous line with sodium chloride 9 mg/mL (0.9%) solution for infusion will ensure that the patient receives the full dose. Do not store any unused infusion solution for use later.