Package leaflet: Information for the user

Simulect® 10 mg powder and solvent for solution for injection or infusion

basiliximab

Read all of this leaflet carefully before you are given 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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Simulect is and what it is used for

Simulect belongs to a group of medicines called immunosuppressants. It is given in hospital to adults, adolescents and children who are having a kidney transplant. Immunosuppressants reduce the body's response to anything that it sees as "foreign" – which includes transplanted organs. The body's immune system thinks a transplanted organ is a foreign body and will try to reject it. Simulect works by stopping the immune cells that attack transplanted organs.

You will only be given two doses of Simulect. These will be given in hospital, around the time of your transplant operation. Simulect is given to stop your body from rejecting the new organ during the first 4 to 6 weeks after the transplant operation, when rejection is most likely. You will be given other medicines to help protect your new kidney during this time, such as ciclosporin and corticosteroids and after you leave hospital.

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

Follow your doctor's instructions carefully. If you are unsure about anything, ask your doctor, nurse or pharmacist.

You must not be given Simulect
- if you are allergic (hypersensitive) to basiliximab or any of the other ingredients of Simulect listed in section 6 under "What Simulect contains". Tell your doctor if you suspect you may have had an allergic reaction to any of these ingredients in the past.
- if you are pregnant or breast-feeding.

Warnings and precautions
Talk to your doctor, nurse or pharmacist before you are given Simulect:
- if you have previously received a transplant that failed after only a short time or,
- if you have previously been in the operating theatre for a transplantation that in the end was not performed.

In this situation, you may have received Simulect. Your doctor will check this for you and discuss with you the possibility of repeated treatment with Simulect.

If you need to have a vaccination, seek your doctor's advice first.

Other medicines and Simulect
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

Older patients (aged 65 years and over)
Simulect can be given to older patients, but the information available is limited. Your doctor may discuss this with you before you are given Simulect.

Children and adolescents (aged 1 to 17 years)
Simulect can be given to children and adolescents. The dose for children who weigh less than 35 kg will be smaller than the dose usually given to adults.

Pregnancy and breast-feeding
It is very important to tell your doctor before your transplant if you are pregnant or you think that you may be pregnant. You must not be given Simulect if you are pregnant. You must use adequate contraception to prevent pregnancy during treatment and up to 4 months after receiving the last dose of Simulect. If you become pregnant during this time, despite the use of contraceptive measures, you should tell your doctor immediately.

You should also tell your doctor if you are breast-feeding. Simulect may harm your baby. You must not breast-feed after being given Simulect or up to 4 months after the second dose.

Ask your doctor, nurse or pharmacist for advice before taking any medicine while you are pregnant or breast-feeding.

Driving and using machines
There is no evidence to indicate that Simulect has an effect on your ability to drive a car or use machines.

Simulect contains sodium and potassium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

This medicine contains potassium, less than 1 mmol (39 mg) per vial, i.e. essentially 'potassium-free'.

3. How Simulect is given

You will only be given Simulect if you are receiving a new kidney. Simulect is given twice, in hospital, either slowly through a needle in your vein as an infusion lasting 20–30 minutes or as an intravenous injection using a syringe.

If you have experienced a severe allergic reaction to Simulect or if you had complications after your surgery such as graft loss, the second dose of Simulect should not be given to you.

The first dose is given just before the transplant operation, and the second dose 4 days after the operation.

Usual dose for children and adolescents (aged 1 to 17 years)
- For children and adolescents who weigh less than 35 kg, the dose of Simulect given in each infusion or injection is 10 mg.
- For children and adolescents who weigh 35 kg or more, the dose of Simulect given in each infusion or injection is 20 mg.

Usual dose for adults
The usual dose for adults is 20 mg in each infusion or injection.

If you are given too much Simulect
An overdose of Simulect is not likely to cause side effects straight away, but it may weaken your immune system for longer. Your doctor will watch out for any effects on your immune system and treat them if necessary.

4. Possible side effects

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

Tell your doctor or nurse as soon as possible if you get any unexpected symptoms while you are being given Simulect, or during the 8 weeks afterwards, even if you do not think that they are related to the medicine.

Sudden severe allergic reactions have been reported in patients treated with Simulect. If you notice sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, fast heart beat, dizziness, light headedness, shortness of breath, sneezing, wheezing or trouble breathing, severely decreased urine output, or fever and flu-like symptoms, tell your doctor or nurse immediately.

In children, the most commonly reported side effects were constipation, excessive growth of normal hair, runny or blocked nose, fever, high blood pressure, and various kinds of infections.

In adults, the most commonly reported side effects were constipation, nausea, diarrhoea, weight increase, headache, pain, swelling of hands, ankles or feet, high blood pressure, anaemia, changes in blood chemistry (e.g. potassium, cholesterol, phosphate, creatinine), surgical wound complications, and various kinds of infections.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Simulect

Keep this medicine out of the sight and reach of children.

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

Store in a refrigerator (2°C - 8°C).

6. Contents of the pack and other information

What Simulect contains
- The active substance is basiliximab. Each vial contains 10 mg of basiliximab.
- The other ingredients are potassium dihydrogen phosphate; disodium phosphate, anhydrous; sodium chloride; sucrose; mannitol (E421); glycine.

What Simulect looks like and contents of the pack
Simulect comes as a white powder in a colourless glass vial containing 10 mg of basiliximab. It is supplied in a pack with a colourless glass ampoule containing 5 ml sterile water for injections. 2.5 ml of the sterile water is used to dissolve the powder before it is given to you.

Simulect is also available in vials with 20 mg basiliximab.

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INSTRUCTIONS FOR RECONSTITUTION AND ADMINISTRATION

The following information is intended for healthcare professionals only:

Simulect 10 mg must not be administered unless it is absolutely certain that the patient will receive the graft and concomitant immunosuppression.

To prepare the solution for infusion or injection, take 2.5 ml water for injections out of the accompanying 5 ml ampoule aseptically and add this 2.5 ml water for injections to the vial containing the Simulect powder, using aseptic technique. Shake the vial gently to dissolve the powder, avoiding foaming. It is recommended that after reconstitution the colourless, clear to opalescent solution should be used immediately. Reconstituted products should be inspected visually for particulate matter prior to administration. Do not use if foreign particles are present. After reconstitution, chemical and physical in-use stability has been demonstrated for 24 hours at 2°C - 8°C or for 4 hours at room temperature. Discard the reconstituted solution if not used within that time. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Reconstituted Simulect is administered as an intravenous infusion over 20 to 30 minutes or as a bolus injection. The reconstituted solution is isotonic. For infusion, the reconstituted solution should be diluted to a volume of 25 ml or greater with normal saline or dextrose 50 mg/ml (5%). The first dose should be given within 2 hours before transplantation surgery, and the second dose 4 days after transplantation. **The second dose should not be given if severe hypersensitivity reactions to Simulect or graft loss occur.**

Since no data are available on the compatibility of Simulect with other intravenous substances, Simulect should not be mixed with other medications/substances and should always be given through a separate infusion line.

Compatibility with the following infusion sets has been verified:

Infusion bag
- Baxter minibag NaCl 0.9%

Infusion sets
- Luer Lock™, H. Noolens
- Sterile vented i.v. set, Abbott
- Infusion set, Codan
- Infusomat™, Braun
- Infusionsgerät R 87 plus, Ohmeda
- Lifecare 5000™ Plumset Microdrip, Abbott
- Vented basic set, Baxter
- Flashball device, Baxter
- Vented primary administration set, Imed

Do not use after the expiry date stated on the pack.

Store in a refrigerator (2°C - 8°C).

Any unused product or waste material should be disposed of in accordance with local requirements.