

SIMULECT®

basiliximab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Simulect.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Simulect against the benefits they expect it will give you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Simulect is used for

Simulect is used for people who have had a kidney transplant, to prevent the body from rejecting the new organ.

Two doses of Simulect injection will be given to you around the time of the transplant operation, while you

are still in hospital. You will also be given other medicines to help protect your new kidney and you will need to continue taking some of these medicines every day after you leave hospital.

Simulect belongs to a group of medicines called immuno-suppressants. These medicines help to control your body's immune system.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you have Simulect

When you must not have it

Do not have Simulect if you have ever had an allergic reaction to basiliximab, the active ingredient in Simulect, or to any of the other ingredients of Simulect listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, fast heart beat, dizziness or light headedness, shortness of breath, wheezing or troubled breathing.

Do not have Simulect if you are pregnant. You must use adequate contraception to prevent pregnancy and continue its use for an additional four months after the last dose of Simulect.

There is no experience with Simulect in pregnancy. As with other immunosuppressant medicines, this

medicine could affect your developing baby.

Before you are given it

Tell your doctor if you are breast-feeding. You must stop breast-feeding while you are having Simulect and for 4 months after you have had the last dose.

It is not known if basiliximab, the active ingredient in Simulect, passes into breast milk and could affect your baby.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

It is possible that some medicines and Simulect could interfere with each other.

Tell your doctor if you have any health problems or medical conditions other than your kidney problems.

If you have not told your doctor about any of these things, tell him/her before you have Simulect.

How Simulect is given

Simulect can either be injected directly into a vein using a syringe or it can be given slowly as an intravenous infusion (drip) over 20 to 30 minutes.

How much is given

You will usually have two doses of Simulect. The first dose is given just before your transplant operation starts, and the second dose is given four days after the operation. 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.

For an adult or a child weighing 35 kg or more, each dose of Simulect is 20 mg. For a child weighing less than 35 kg, each dose of Simulect is 10 mg.

If you are given too much (Overdose)

If you think that you may have been given too much Simulect, immediately tell your doctor or nurse.

No cases of overdose with this medicine have been reported. If an overdose occurs, it should not cause immediate side effects but it may increase the time that the activity of your immune system is reduced. Your doctor will watch for any effects and treat them if necessary.

While you are having Simulect

Things you must do

If you find out that you are pregnant while you are having Simulect or in the four months following the last dose, tell your doctor immediately.

Your doctor can discuss with you the risks this medicine may have for your developing baby.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Simulect until you know how it affects you.

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Simulect, or for 8 weeks afterward, even if you do not think it is connected with the medicine.

Sudden severe allergic reactions have been reported in patients treated with Simulect.

Tell your doctor or nurse immediately if you notice any of the following signs of a possible allergic reaction to Simulect:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- fast heart beat
- dizziness or light headedness
- shortness of breath, sneezing, wheezing or troubled breathing
- severe decrease in urine output
- fever and flu-like symptoms

Allergic reactions are rare but have serious side effects that may require urgent medical attention. Your doctor or nurse will have medicines to treat this type of reaction near at hand.

Generally, patients who have had a kidney transplant take several medicines as well as Simulect. You may get some side effects from your medicines or feel unwell after your transplant.

Tell your doctor if you notice any of the following symptoms and they worry you:

- pain
- fever
- shaking
- swelling of hands, ankles or feet due to fluid retention
- headache
- difficulty sleeping
- change in bowel habits (constipation or diarrhoea)
- pain in the abdomen
- nausea (feeling sick) or vomiting
- difficulty or pain on urinating, which may be signs of a urinary infection

- runny or blocked nose, sore throat or cough, which may be signs of an infection of the respiratory system
- weight increase
- increase in blood creatinine (which may cause dehydration, fatigue, shortness of breath and confusion)
- low phosphate levels in the blood (this will be measured by your doctor)

The above list includes side effects that were commonly reported during clinical trials of Simulect.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people. Some side effects such as changes in your blood chemistry (e.g. iron, cholesterol or potassium levels) or in your blood pressure may only be detected when you have tests during your stay in hospital.

Product description

What it looks like

Simulect is a sterile powder supplied in a glass vial. An ampoule containing 5 mL of sterile water, which is used to dissolve the powder before injection, is also provided in the pack.

Ingredients

Each vial of Simulect contains 20 mg of the active ingredient, basiliximab. It also contains:

- potassium phosphate monobasic
- sodium phosphate dibasic anhydrous
- sodium chloride
- sucrose
- mannitol
- glycine

Sponsor

Simulect is supplied in Australia by:

NOVARTIS Pharmaceuticals

Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

North Ryde NSW 2113

Telephone: 1 800 671 203

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This leaflet was prepared in

June 2011.

Australian Registration Number.

Simulect AUST R 66740

(sml130715c.doc) based on PI

(sml130715i.doc)