

PART III: CONSUMER INFORMATION

PrSIMULECT®
(basiliximab)

This leaflet is part III of a three-part "Product Monograph" published when SIMULECT® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SIMULECT®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

What SIMULECT® is:

SIMULECT® is an immunosuppressant.

What the medication is used for:

SIMULECT® is given to adults who are having a kidney transplant. It helps to prevent rejection of the transplanted kidney during the first 4 to 6 weeks after the transplant operation, which is the time when the body is most likely to try to reject the kidney. You will be given other medicines to help protect your new kidney during this time (for instance, cyclosporine for microemulsion), and you will need to continue taking some of these medicines every day after you leave the hospital. SIMULECT® is given to you only around the time of your transplant operation.

What it does:

SIMULECT® is a type of medicine known as an immunosuppressant. Immunosuppressants reduce the body's response to things that it recognises as "foreign", such as transplanted organs. SIMULECT® works to prevent your immune system from creating the specific cells that attack a transplant and lead to the body rejecting it. SIMULECT® binds to a certain type of white blood cell called a lymphocyte. These specific lymphocytes play a central role in the rejection reaction.

When it should not be used:

You should not be given SIMULECT®:

If you have had an allergic reaction to basiliximab, mouse cell proteins or to any of the other ingredients of SIMULECT® listed below under the heading "What the medicinal and non-medicinal ingredients are". Tell your doctor if you suspect you may have had an allergic reaction to any of these ingredients in the past.

Use in older people (aged 65 years and over)

SIMULECT® can be given to elderly people. Although experience with use of SIMULECT® in the elderly is limited, there is no evidence to suggest that any special precautions are needed when elderly people are treated.

Use in Pregnancy and breast-feeding

Tell your doctor before your transplant operation if you are pregnant or think that you may be pregnant. You should not be given SIMULECT® if you are pregnant unless the potential benefits are thought to be greater than the possible risks.

Tell your doctor if you are breast-feeding. basiliximab, the active ingredient of SIMULECT®, may pass into your milk and affect your baby. Do not breast-feed after having SIMULECT® or in the 4 months after the last dose.

Use in women of child-bearing potential

Use adequate contraception to prevent pregnancy and continue its use for an additional 4 months after the last dose of SIMULECT®.

Use in Pediatric Patients

No adequate and well-controlled studies have been completed in pediatric patients. Safety and efficacy in pediatric patients have not been established and pharmacokinetic data is very limited. No studies have been performed in neonates or children aged less than two years.

Driving and using machines

SIMULECT® is not expected to affect your ability to drive or use machines.

What the medicinal ingredient is:

The active ingredient of SIMULECT® is called

basiliximab.

What the nonmedicinal ingredients are:

Potassium dihydrogen phosphate, disodium phosphate anhydrous, sodium chloride, sucrose, mannitol, glycine, and sterile water (when prepared for use).

These are standard inactive ingredients that are needed for storing SIMULECT® and for preparing it for intravenous use.

What dosage forms it comes in:

SIMULECT® is supplied in vials, which each contain 20 mg basiliximab.

WARNINGS AND PRECAUTIONS

Tell your doctor or nurse as soon as possible if you notice any unexpected symptoms while you are being given SIMULECT®, or for 4 months afterwards, even if you do not think that they are connected with the medicine (See Side Effects and What to do about them).

Take special care with 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 these situations, 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 receive a vaccine, seek your doctor's advice first.

INTERACTIONS WITH THIS MEDICATION

- SIMULECT® should not change the way other medicines work, nor should other medicines change the way SIMULECT® works.
- Nonetheless, it is important that you tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

PROPER USE OF THIS MEDICATION

Usual dose:

The usual dose of SIMULECT® given in each infusion or intravenous injection is 20 mg.

Normally, you will be given two doses of ~~Simulect~~ SIMULECT®. The first dose is given just before your transplant operation starts, and the second dose is given 4 days after the operation. A doctor or nurse will give the treatment, since SIMULECT® has to be injected into a vein. It can be either injected directly using a syringe, or given slowly as an infusion lasting 20-30 minutes.

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

Overdosage

If you are given more SIMULECT® than you should

An overdose of SIMULECT® should not cause immediate side effects, but it may lengthen the time during which the activity of the immune system is reduced. If you are given too much SIMULECT®, your doctor will watch for any consequences of this effect on your immune system and treat them if necessary.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, SIMULECT® can have side effects, although not everybody gets them.

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 and light headedness, shortness of breath, sneezing, wheezing or trouble breathing, a severe decreased urine output, or anything new, such as fever and flu-like symptoms, tell your doctor or nurse immediately.

You will probably be taking several medicines in addition to SIMULECT®. You may get side effects from these or feel unwell after your transplant.

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 (potassium, cholesterol, phosphate, creatinine), surgical

wound complications, and different kinds of infections.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist right away		Stop taking drug and seek immediate emergency medical assistance
		Only if severe	In all cases	
Common	constipation,	√		
	nausea,	√		
	diarrhea,	√		
	weight increase,	√		
	headache,	√		
	pain,	√		
	swelling of hands, ankles or feet,	√		
	high blood pressure,		√	
	anaemia, changes in blood chemistry (potassium, cholesterol, phosphate, creatinine),	√		
	surgical wound complications,	√		
	different kinds of infections.	√		
Uncommon	rash, itching or hives on the skin,	√		
	swelling of the face, lips, tongue or other parts of the body,		√	

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	Only if severe	In all cases	
fast heart beat, dizziness and light headedness,	√		
shortness of breath,		√	
sneezing,	√		
wheezing or trouble breathing,		√	
a severe decreased urine output,		√	
anything new, such as fever and flu-like symptoms	√		

This is not a complete list of side effects. For any unexpected effects while taking SIMULECT®, contact your doctor or pharmacist.

HOW TO STORE IT

SIMULECT® should be stored under refrigerated conditions at 2-8 °C. The reconstituted solution can be kept at 2-8 °C for 24 hours or at room temperature for 4 hours, but for bacteriological reasons it should be used as soon as possible.

- Do not use after the expiry date shown on the box.
- Store in the original package.
- Do not use any SIMULECT® pack that is damaged or shows signs of tampering.
- Keep out of the reach and sight of children.

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SIMULECT is a registered trademark.

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REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

**Report online at www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345**

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or**
- Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 0701D
 Ottawa, Ontario
 K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.Novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:

1-800-363-8883

This leaflet was prepared by
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