

SIMULECT®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor, nurse, or pharmacist.

1. Why am I given SIMULECT?

SIMULECT contains the active ingredient basiliximab. SIMULECT is used when you are receiving a new kidney from a transplant to reduce the likelihood of your body rejecting

For more information, see Section [1. Why am I given SIMULECT?](#) in the full CMI.

2. What should I know before given SIMULECT?

Do not use if you have ever had an allergic reaction to SIMULECT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines or have had some vaccines recently, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before given SIMULECT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SIMULECT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I receive SIMULECT?

- SIMULECT will be given to you in a hospital by a doctor or nurse

SIMULECT is administered directly into your vein. More instructions can be found in Section [4. How do I receive SIMULECT?](#) in the full CMI.

5. What should I know while given SIMULECT?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you have had SIMULECT before. Use effective contraception to avoid
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	becoming pregnant
Things you should not do	<ul style="list-style-type: none"> • Do not become pregnant or breastfeed
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or use machinery until you know how SIMULECT affects you.

For more information, see Section [5. What should I know while given SIMULECT?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include dry or cracked lips, feeling sick, tired, or confused, headache, change in weight, swelling of hands or feet, trouble sleeping, infections or flu-like symptoms, shaking hands. More serious side effects include signs of an allergic reaction including swelling of lips or tongue, spreading of rash or blisters, breathing difficulties including wheezing or trouble breathing or fast heartbeat, less wee than normal; less wee than normal going to the toilet.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SIMULECT® (Sim-u-lect)

Active ingredient: *basiliximab* (bas-ee-licks-ee-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SIMULECT. **You should also speak to your doctor, nurse, or pharmacist if you would like further information or if you have any concerns or questions about using SIMULECT.**

Where to find information in this leaflet:

- [1. Why am I given SIMULECT?](#)
- [2. What should I know before given SIMULECT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive SIMULECT?](#)
- [5. What should I know while given SIMULECT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given SIMULECT?

SIMULECT contains the active ingredient basiliximab.

SIMULECT is a type of medicine known as an immunosuppressant. Immunosuppressants reduce the body's response to things that it recognises as "foreign" - including 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.

SIMULECT is given to adults, adolescents and children who are having a kidney transplant. It helps 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, ciclosporin), 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.

2. What should I know before given SIMULECT?

Warnings

Do not use SIMULECT if:

- you are allergic to basiliximab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- if you are pregnant or breast-feeding.

Check with your doctor if you:

- take any other medicines for any other condition
- have blood cancer ('lymphoma')
- have previously received a transplant that failed after only a short time or,
- have used this medicine before.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

It is very important to tell your doctor before your transplant operation if you are pregnant, think that you may be pregnant, or intend to become 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. 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 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.

Vaccination

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

3. What if I am taking other medicines?

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

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.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SIMULECT.

4. How do I receive SIMULECT?

How much is given

- The usual dose is 20 mg in each infusion or injection.
- For children and adolescents who weigh less than 35 kg, the dose given in each infusion or injection is 10 mg.

When to receive SIMULECT

- You will only be given SIMULECT if you are receiving a new kidney.
- Normally, you will be given two doses of SIMULECT in hospital. 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 you 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 to 30 minutes.

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.

5. What should I know while given SIMULECT?

Call your doctor straight away if:

you find out that you are pregnant while you are given SIMULECT or in the four months following the last dose.

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

Driving or using machines

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

6. Are there any side effects?

All medicines can have side effects. 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

The lists below include side effects that were commonly reported during clinical trials of SIMULECT.

Less serious side effects

Less serious side effects	What to do
<p>In adults:</p> <ul style="list-style-type: none">• Change in toilet habits• Nausea (feeling sick) or vomiting• Weight increase• Headache• Pain• Swelling of hands, ankles or feet• High blood pressure• Anaemia• Dry or cracked lips which may be symptoms of dehydration• Feeling tired, weak or confused• Feeling breathless• Surgical wound complications• Trouble sleeping• Various kinds of infections	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Shaking hands <p>In children:</p> <ul style="list-style-type: none"> ● Constipation ● Excessive growth of normal hair ● Runny or blocked nose ● Fever ● High blood pressure ● Various kinds of infections 	

Serious side effects

Serious side effects	What to do
<p>Signs of sudden severe allergic reactions:</p> <ul style="list-style-type: none"> ● Rash ● Itching or hives on the skin ● Swelling of the face, lips, tongue, or other parts of the body ● Fast heartbeat ● Dizziness or light-headedness ● Shortness of breath 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Sneezing, wheezing or trouble breathing ● Less wee than normal when using the toilet. ● Fever and flu-like symptoms 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SIMULECT contains

Active ingredient (main ingredient)	basiliximab
Other ingredients (inactive ingredients)	monobasic potassium phosphate dibasic sodium phosphate sodium chloride sucrose mannitol glycine
Potential allergens	<p>Simulect contains sodium and potassium.</p> <p>This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.</p> <p>This medicine contains potassium, less than 1 mmol (39 mg) per vial, i.e. essentially 'potassium-free'</p>

Do not take this medicine if you are allergic to any of these ingredients.

What SIMULECT looks like

SIMULECT is a sterile powder supplied in a glass vial. Not all marketed presentations include an ampoule containing 5 mL of sterile water to dissolve the powder before injection.

Who distributes SIMULECT

SIMULECT is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone: 1 800 671 203

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