

Certican®

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 or pharmacist.

1. Why am I using Certican?

Certican contains the active ingredient everolimus. Certican is used to treat adult patients who have had kidney, heart or liver transplants. It helps to prevent your body from rejecting the transplanted organ. For more information, see Section [1. Why am I using Certican?](#) in the full CMI.

2. What should I know before I use Certican?

Do not use if you have ever had an allergic reaction to Certican 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 are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Certican?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Certican 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 use Certican?

- Kidney and heart transplant: the usual starting dose is 0.75 mg Certican twice a day, with ciclosporin. The first dose of Certican is taken as soon as possible after transplantation.
- Liver transplant: the recommended dose is 1 mg Certican taken twice a day, with tacrolimus and a corticosteroid. The first dose of Certican is taken approximately four weeks after transplantation.

More instructions can be found in Section [4. How do I use Certican?](#) in the full CMI.

5. What should I know while using Certican?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using Certican.
- If you develop lumps anywhere in your body, or develop any moles, or you notice changes in

	<p>existing moles, tell your doctor.</p> <ul style="list-style-type: none"> ● If you go out in the sun, wear a hat, protective clothing and sunscreen. Do not use a sun lamp. ● If you want to be vaccinated, tell your doctor you are taking Certican before you have the vaccination. ● Make sure you use a highly effective contraceptive to prevent pregnancy during treatment with Certican.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take Certican to treat any other complaints unless your doctor tells you to. ● Do not give your medicine to anyone else, even if they have the same condition as you.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how Certican affects you.

Looking after your medicine

- Keep the tablets in the original packet and foils until it is time to take them.
- Store the tablets in a cool, dark and dry place at room temperature.

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

6. Are there any side effects?

Common side effects: general pain, muscle or joint pain or tenderness, abdominal pain, nausea, vomiting, diarrhoea, headache, nosebleeds, acne, weakness, bruising and frequent infections. **Serious side effects:** swelling of hands, feet or limbs, burning sensation on urination, unusual bleeding or bruising, persistent or worsening lung/breathing problems. 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.

Certican®

Active ingredient(s): *everolimus*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Certican?

Certican contains the active ingredient everolimus. Certican belongs to a group of medicines called immunosuppressants. These medicines help to control your body's immune system.

Certican is used to treat adult patients who have had kidney, heart or liver transplants. It helps to prevent your body from rejecting the transplanted organ.

2. What should I know before I use Certican?

Warnings

Do not use Certican if:

- you are allergic to everolimus, or any of the ingredients listed at the end of this leaflet
- you are allergic to a similar medicine called sirolimus (Rapamune)

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; sudden difficulty swallowing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions, such as:
 - problems with your liver
 - high cholesterol
- take any medicines for any other condition

- are intolerant to certain sugars called glucose, galactose, lactose. Certican tablets contain lactose.
- have allergies to any other medicines, foods, preservatives or dyes.
- have had recent major surgery, or if you still have an unhealed wound following surgery. Certican may increase the risk of problems related to wound-healing.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Effective contraceptive methods should be taken while you are taking Certican and up to 8 weeks after stopping treatment.

Certican is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding.

Breastfeeding is not recommended while you are taking Certican. It is not known whether this medicine passes into breast milk and could affect your baby.

Fertility

Talk to your doctor if you plan to have children.

It is unknown if Certican may cause infertility in male and female patients. In male patients, it may reduce sperm production, thus reducing the ability to father children. The effect is generally reversible.

3. What if I am taking other medicines?

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

Some medicines may interfere with Certican and affect how it works. These include:

- Ciclosporin, used to prevent transplant rejection and often taken with Certican
- Antibiotics such as rifampicin, clarithromycin, erythromycin and rifabutin
- Antifungal medicines such as ketoconazole, fluconazole and itraconazole
- Medicines for high blood pressure or heart problems such as diltiazem and verapamil
- Medicines used to treat HIV/AIDS such as efavirenz and nevirapine
- Medicines used to lower blood cholesterol, such as atorvastatin, pravastatin or fibrates

- Midazolam, a medicine used as a sedative before or during surgery or other medical procedure.
- Epilepsy medicines such as carbamazepine, phenobarbitone and phenytoin
- Cannabidiol used to treat epilepsy and chronic pain, and to improve symptoms related to muscle stiffness and spasms in multiple sclerosis
- Medicines for stomach ulcer or reflux such as cimetidine and cisapride
- Medicines to prevent nausea and vomiting such as metoclopramide
- Danazol which is used to treat endometriosis
- Bromocriptine which is used to treat Parkinson's disease
- St John's wort, a herbal product used for depression and other conditions.

Such medicines may be affected by Certican or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Some vaccines may be less effective if given when taking Certican.

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

4. How do I use Certican?

How much to take

Kidney and heart transplant

- The usual starting dose is one Certican 0.75 mg tablet taken twice a day, with ciclosporin.
- The first dose of Certican is usually taken as soon as possible after transplantation.

Liver transplantations

- The recommended dose is one Certican 1 mg tablet taken twice day, with tacrolimus and corticosteroids.
- The first dose of Certican is usually taken approximately four weeks after transplantation.

Your doctor will take regular blood tests to measure the amount of Certican in your blood. If needed, your doctor will adjust your dose depending on the results from your blood test.

If you need to take other medicines in combination with Certican, your doctor will tell you how much to take.

When to take Certican

Always take Certican twice a day. It is best to take the doses 12 hours apart if possible, once in the morning and once in the evening.

Taking your doses 12 hours apart and at the same time each day will have the best effect. It will also help you remember when to take them.

Certican can be taken with or without food but should always be taken the same way. (e.g. always with food or always without food). However, do not take Certican with grapefruit or grapefruit juice.

If you are taking ciclosporin, tacrolimus or a corticosteroid, take them as directed by your doctor.

How to take Certican

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew them.

How long to take Certican

Keep taking this medicine for as long as your doctor tells you.

You will need to take this medicine as long as you have your transplanted organ, or until your doctor changes your immunosuppressive medication.

If you forget to take Certican

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you miss more than one dose, ask your doctor for advice.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much Certican

If you think that you have taken too much Certican, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Certican?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

Regular check-ups with blood and urine tests are essential for your doctor to assess the function of your transplanted organ, to detect possible unwanted side effects and to adjust the dose of your medicines for the best treatment.

See your doctor if you develop any of the following symptoms:

- a fever or generally feel unwell, or have symptoms such as coughing or a burning sensation when urinating that are severe or continue over several days
- feel confused, have problems speaking, memory loss, a headache, impaired vision or seizures, as these may be symptoms of a rare but very serious condition called progressive multiple leukoencephalopathy (PML).

Use a highly effective contraceptive to prevent pregnancy during treatment with Certican.

Effective contraceptive methods should be taken while you are taking Certican and up to 8 weeks after stopping treatment.

Tell your doctor straight away if you become pregnant while taking this medicine.

Limit your exposure to sunlight by wearing a hat, protective clothing and sunscreen when you go out in the sun. Do not use a sun lamp.

This will help to prevent the development of skin cancer.

Immunosuppressant medicines, including Certican, may increase the risk of developing certain cancers, including skin cancer and lymphoma (cancer of the lymphatic system).

If you develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles, tell your doctor. These may be an early sign of a skin cancer.

If you need to be vaccinated, tell your doctor you are taking Certican before you have the vaccination.

Certican may affect your response to vaccination. Some vaccines may not be suitable for you.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Certican.

Remind any doctor, dentist or pharmacist you visit that you are using Certican.

Things you should not do

- Do not take Certican to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking Certican or change the dose unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Certican affects you.

Looking after your medicine

- Keep the tablets in the original packet and foils until it is time to take them.

Store it in a cool dry place at room temperature away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut or Gastrointestinal related</p> <ul style="list-style-type: none">• abdominal pain• nausea, vomiting, diarrhoea, constipation <p>Infection related</p> <ul style="list-style-type: none">• cough, sore throat, feeling tired, fever• burning sensation on urination or increased urgency to urinate• wounds taking longer than normal to heal <p>Mood or brain related</p> <ul style="list-style-type: none">• trouble sleeping	<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"> ● feeling more worried than normal <p>Skin related</p> <ul style="list-style-type: none"> ● acne ● rash ● cold sores, mouth sores ● fluid filled swelling on the skin <p>General</p> <ul style="list-style-type: none"> ● general pain, muscle or joint pain or tenderness ● headache ● nosebleeds ● reduced sexual desire, problems with erection and ejaculation in males ● absent or heavy periods in females ● pain around the pelvis, bloating or discomfort in the abdomen ● pain in the ear, nose or throat ● increased heart rate. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● signs of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat which may cause difficulty in swallowing or breathing; rash, itching or hives on the skin● persistent or worsening symptoms of coughing, difficulty breathing, wheezing● swelling of hands, feet or limbs● constant "flu-like" symptoms such as fever (increased temperature), chills/shivering, sore throat, aching joints, swollen glands, cough● slow wound healing or infection of a wound● severe upper stomach pain, which may be	<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
<p>accompanied by nausea and vomiting</p> <ul style="list-style-type: none"> ● new lumps or moles, or changes to existing moles, anywhere on the body ● unusual bleeding or bruising without obvious cause ● tiredness, headaches, shortness of breath when exercising, dizziness and looking pale, which could be signs of anaemia ● severe sudden headache, sudden loss of coordination, blurred vision, loss of vision, slurred speech, numbness in an arm or leg, pain in the calves, thighs or chest, shortness of breath, coughing blood. ● yellowing of the skin and eyes with darkened urine ● sudden reduction in your urine output, especially 	

Serious side effects	What to do
<p>if accompanied by pain where your transplanted kidney is located.</p> <ul style="list-style-type: none"> • pain, hernia, unusual warmth, swelling or oozing from the site of surgery. 	

In addition, your doctor will do blood tests to check your kidneys to make sure they are not being damaged during treatment with Certican.

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. Some of these side effects can only be found by laboratory testing (e.g. high blood level of sugar, high cholesterol, low potassium levels).

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 Certican contains

Active ingredient (main ingredient)	everolimus
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• butylated hydroxytoluene• magnesium stearate• lactose• hypromellose• crospovidone• lactose anhydrous
Potential allergens	<ul style="list-style-type: none">• Milk sugars in the form of lactose and galactose. <p>This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.</p>

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

What Certican looks like

Certican tablets are white to yellowish, round and marbled. Certican tablets are available in four different strengths, supplied in packs of 60 tablets:

Certican 0.25mg – with "C" on one side and "NVR" on the other (Aust R 97500).

Certican 0.5mg – with "CH" on one side and "NVR" on the other (Aust R 97506).

Certican 0.75mg – with "CL" on one side and "NVR" on the other (Aust R 97509).

Certican 1mg – with "CU" on one side and "NVR" on the other (Aust R 97516).

Who distributes Certican

Novartis Pharmaceuticals Australia Pty Limited

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54 Waterloo Road

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