

Certican®

everolimus

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Certican.

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 taking Certican against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Certican is used for

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.

Certican contains the active ingredient everolimus. It belongs to a group of medicines called immunosuppressants. 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.

Certican is available only with a doctor's prescription and is not addictive.

There is not enough information to recommend the use of this medicine in children and adolescents.

Before you take Certican

When you must not take it

Do not take Certican if you have an allergy to:

- everolimus, the active ingredient in Certican
- any of the ingredients listed at the end of this leaflet.
- a similar medicine called Rapamune which contains the active ingredient sirolimus.

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.

Do not take this medicine after the expiry date printed on the

pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have or have had any of the following medical conditions:

- problems with your liver
- high cholesterol

Tell your doctor if you are pregnant or plan to become pregnant.

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

Tell your doctor if you are breast-feeding.

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

Tell your doctor if you are male and you want to father children.

Certican may reduce sperm production in men, thus reducing the ability to father children. The effect is generally reversible.

Tell your doctor if you are male or female and you want children.

Certican may cause infertility in male or female patients.

Tell your doctor if you have intolerance to certain sugars (glucose, galactose, lactose).

Certican tablets contain lactose.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies.

Medicines that suppress the immune system like Certican reduce your body's ability to fight against infections. It is advisable to consult your doctor if you have a fever or generally feel unwell, or have local symptoms such as coughing or a burning sensation when urinating that are severe or persistent over several days.

Consult your doctor right away if you 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).

Tell your doctor if you have had recent major surgery, or if you still have an unhealed wound following surgery.

Certican may increase the risk of wound-healing problems.

If you have not told your doctor about any of the above, tell him/her before you start taking Certican.

Taking other medicines

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

Some medicines and Certican may interfere with each other. These include:

- Immunosuppressive medicines other than cyclosporin for microemulsion, tacrolimus or corticosteroids.
- 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
- dronedarone, a medicine used to help regulate your heart beat
- Medicines used to treat HIV/AIDS such as nelfinavir, indinavir, amprenavir, efavirenz and nevirapine
- medicines used to lower blood cholesterol, such as atorvastatin, pravastatin or fibrates
- Midazolam, a medicine used to treat acute seizures, or used as a sedative before or during surgery or other medical procedure.
- Epilepsy medicines such as carbamazepine, phenobarbitone and phenytoin
- octreotide, a medicine used to treat acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults
- 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
- imatinib, a medicine used to inhibit the growth of abnormal cells
- St John's wort, a herbal product used to treat 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Certican

Certican tablets are swallowed whole.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label ask your doctor or pharmacist for help.

How much to take

Kidney and heart transplantations

The usual starting dose is 0.75 mg Certican twice daily, taken in the morning and in the evening together with cyclosporine.

The first dose of Certican will be given as soon as possible after transplantation.

Liver transplantation:

The general recommended daily dose is 1 mg Certican twice daily, taken in the morning and in the evening, together with tacrolimus.

The first dose of Certican will be given 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 tests.

When to take it

Always take Certican twice a day. It is best to take the doses 12 hours apart if possible.

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).

If you are taking cyclosporine or tacrolimus, you should take it at the same time as Certican.

How to take it

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

How long to take it

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

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

If you forget to take it

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 that 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Certican. Do this even if there are no signs of discomfort or poisoning.

While you are taking Certican

Things you must 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 good function of your transplanted organ, to detect possible unwanted side effects and to adapt the dosages of your medicines to obtain the best treatment.

Blood tests allow your doctor to measure levels of your medicines to check your kidney activity and the levels of sugar and cholesterol in your blood.

Measurement of proteins in a urine sample also helps your doctor to assess kidney activity.

Make sure you use a highly effective contraceptive to prevent pregnancy during treatment with Certican. If you become pregnant while taking this medicine, tell your doctor immediately.

If you develop lumps anywhere in your body, or develop any moles, or you notice changes in existing moles, tell your doctor.

This may be an early sign of a 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 go out in the sun, wear a hat, protective clothing and sunscreen. Do not use a sun lamp.

This will help to prevent the development of skin cancer.

If you want 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 experiencing respiratory symptoms (e.g. coughing, difficulty

in breathing and wheezing), please inform your doctor. Your doctor may decide whether and how you need to continue Certican, and/or whether you need to receive other medicines to resolve this condition.

Tell your doctor if you experience any swelling of the limbs or around your abdomen.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how Certican affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Certican.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- general pain, muscle or joint pain or tenderness

- weakness, bruising and frequent infections
- upper and lower respiratory tract infections
- urinary tract infections
- slowed wound healing or wound infection
- nosebleeds
- acne
- abdominal pain
- nausea, vomiting, diarrhoea
- impotence
- menstrual disorders (including absent or heavy periods)
- cold sores, mouth sores
- pain in the ear, nose or throat
- jaundice (yellowing of the skin and eyes with darkened urine).
- difficulty sleeping
- anxiety
- headache
- fever
- rash
- increased heart rate
- breathlessness
- ovarian cyst

If any of the following happen, tell your doctor immediately:

- swelling of hands, feet or limbs due to fluid retention
- symptoms of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- burning sensation on urination or increased urgency to urinate
- severe upper stomach pain, which may be accompanied by nausea and vomiting
- constant "flu-like" symptoms such as fever (increased temperature), chills/shivering, sore throat, aching joints, swollen glands, cough, or any other signs of infection such as infection of a cut or scratch
- new lumps or moles, or changes to existing moles, anywhere on the body

- unusual bleeding or bruising without obvious cause
- persistent or worsening lung/breathing symptoms like coughing, difficulty breathing, wheezing
- pain, hernia, unusual warmth, swelling or oozing from the site of surgery
- tiredness, headaches, shortness of breath when exercising, dizziness and looking pale, which could be signs of anaemia
- swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing
- sudden reduction in your urine output, especially if accompanied by pain where your transplanted kidney is located.
- signs that blood clots may have formed, such as 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.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

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 if you notice anything else that is making you feel unwell.

Other side effects not listed here or not yet known may happen in some people. Some of these side effects can only be found by laboratory testing (e.g. blood level of sugar, fat and cholesterol).

After taking Certican

Storage

- 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.
- Do not store Certican or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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:

- 0.25 mg: with "C" on one side and "NVR" on the other
- 0.5 mg: with "CH" on one side and "NVR" on the other
- 0.75 mg: with "CL" on one side and "NVR" on the other
- 1.0 mg: with "CU" on one side and "NVR" on the other

Ingredients

Certican tablets contain 0.25, 0.5, 0.75 mg and 1.0 mg of everolimus as the active ingredient. They also contain:

- butylated hydroxytoluene

- magnesium stearate
- lactose
- hypromellose
- crospovidone
- lactose anhydrous

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Contains lactose, galactose, milk, sugars

Sponsor

Certican 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

® = Registered Trademark

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0.75 mg tablets - AUST R 97509

1.0 mg tablets - AUST R 97516

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