

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrCERTICAN®

(everolimus)

This Patient Medication Information is written for the person who will be taking **CERTICAN®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CERTICAN**, talk to a healthcare professional.

Serious warnings and precautions box

- CERTICAN should only be prescribed and managed by healthcare professionals who are experienced in immunosuppressive therapy and managing organ transplants.
- Taking immunosuppressants, like CERTICAN, can increase the risk of infections and developing lymphoma or skin cancer.
- CERTICAN can cause kidney damage when used with cyclosporine at full doses. If you are taking these drugs, your healthcare professional may need to adjust your dose and order blood tests to monitor your health.
- There is a risk of kidney clots known as thrombosis. This may result in graft loss (transplant failure). This has been reported mostly within the first 30 days post-transplantation.

What CERTICAN is used for:

- CERTICAN (everolimus) is used to prevent your body from rejecting your transplanted organ.
- CERTICAN is used together with medicines called basiliximab and cyclosporine (NEORAL) and corticosteroids to prevent rejection of transplanted kidneys.

How CERTICAN works:

CERTICAN (everolimus) belongs to a group of medicines known as immunosuppressants.

In order to prevent organ rejection, CERTICAN slows down the activity of white blood cells which act to get rid of the transplanted organ.

The ingredients in CERTICAN are:

Medicinal ingredient: everolimus

Non-medicinal ingredients: butylated hydroxytoluene
crospovidone
hypromellose
lactose anhydrous

lactose monohydrate

magnesium stearate

CERTICAN comes in the following dosage forms:

CERTICAN is available as 0.25 mg, 0.5 mg, 0.75 mg tablets.

CERTICAN 0.25 mg tablets are white to yellowish, marbled, round, flat with bevelled edge, engraved “C” on one side and “NVR” on the other.

CERTICAN 0.5 mg tablets are white to yellowish, marbled, round, flat with bevelled edge, engraved “CH” on one side and “NVR” on the other.

CERTICAN 0.75 mg tablets are white to yellowish, marbled, round, flat with bevelled edge, engraved “CL” on one side and “NVR” on the other.

CERTICAN tablets are supplied in packs containing 60 tablets.

Do not use CERTICAN if:

- You are hypersensitive (allergic) to everolimus, sirolimus or to any of the other components that make up CERTICAN. See “The ingredients in CERTICAN are” section, above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CERTICAN. Talk about any health conditions or problems you may have, including if you:

- Have problems of galactose intolerance, Lapp lactase deficiency or glucose/galactose malabsorption, as this product contains lactose.
- Have, or have had any liver problems, as the healthcare professional may modify the CERTICAN dose.
- Are pregnant or **think you are pregnant**. CERTICAN should not be used in pregnancy unless your doctor feels this is necessary. You should use an effective contraceptive before, during and for 8 weeks after taking CERTICAN.
- Are breastfeeding or **thinking of breastfeeding**. It is not known if CERTICAN passes into human breastmilk. You should avoid breastfeeding while taking CERTICAN.
- Are male and want to father children. CERTICAN may reduce sperm production in men which may reduce the ability to have children. Discuss with your healthcare professional.

Other warnings that you should know:

Infections:

Tell your doctor immediately if the following develop while taking CERTICAN:

- Swelling of the face, throat or tongue.
- Skin bruising without obvious cause.
- Pain, hernia, swelling, oozing or unusual warmth at the site of surgery.
- Difficulty in breathing, wheezing, coughing. Your doctor may decide on other of further treatments.
- Fever, malaise, fatigue, burning sensation when urinating, cough as CERTICAN may suppress your immune system and reduce your body’s ability to fight infections.

Vaccines:

You should avoid receiving live vaccines while taking CERTICAN. Close contact with those who have received live vaccines should also be avoided during your treatment.

Sun Exposure:

Immunosuppressants such as CERTICAN may increase the risk of developing cancers, particularly of the skin and lymphoid system. Therefore, you should limit your exposure to sunlight and UV light by wearing appropriate protective clothing and frequently applying sunscreen with a high protection factor.

Diabetes:

CERTICAN may increase the risk of developing diabetes mellitus after transplant. Your doctor will monitor your blood glucose during your treatment.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Please inform your doctor if you are taking or have recently taken any other medicines, even those you have obtained without a prescription.

Some medicines may interfere with the action of CERTICAN or CERTICAN may interfere with other drugs. In particular, you should inform your doctor if you are taking one of the following medicines:

- Live vaccines.
- Immunosuppressive medicines other than cyclosporine microemulsion or corticosteroids.
- Antibiotics or antifungal medicines used to treat infections, e.g. amphotericin B, clarithromycin, telithromycin, ketoconazole, itraconazole, erythromycin, voriconazole, fluconazole.
- Medicines used to treat tuberculosis like rifampicin or rifabutin.
- *Hypericum perforatum* (St. John's Wort) – a herbal product used to treat depression and other conditions.
- Anti convulsants such as phenytoin, carbamazepine, phenobarbital.
- Calcium channel blockers such as verapamil, nifedipine, diltiazem, used to treat heart conditions or high blood pressure.
- Protease inhibitors such as nelfinavir, indinavir, zalcitabine, anti-HIV drugs such as zidovudine, efavirenz, nevirapine used to treat AIDS.
- HMG-CoA reductase inhibitors used to treat high blood cholesterol such as simvastatin, lovastatin, atorvastatin and pravastatin as these medicines may interfere with cyclosporine which is used in this combination treatment.
- Midazolam, a medicine used to treat acute seizures or used as a sedative before or during surgery or other medicinal procedures.
- Octreotide, a medicine used to treat acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults.

Do not take CERTICAN with grapefruit or grapefruit juice since this can interfere with certain enzymes in the body that influence CERTICAN's effects.

How to take CERTICAN:

- CERTICAN is for oral use only.
- Your initial dose should be taken as soon as possible after transplantation.
- Swallow the tablets whole with a glass of water. Do not crush CERTICAN tablets before use.
- CERTICAN should be taken with or without food at the same time as your dose for cyclosporine. Take your doses consistently.
- Your treatment will continue for as long as you need immunosuppression to prevent you from rejecting your transplanted organ.
- Do not stop taking your medicine unless your healthcare professional tells you to. Stopping your treatment with CERTICAN may increase the chance of rejection of your transplanted organ.
- Your healthcare professional will perform blood tests to monitor your dosage. Your doctor will also carefully monitor your kidney function, blood lipids, blood sugar as well as the amount of proteins in your urine.
- Your healthcare professional will decide exactly what dose of CERTICAN is best for you. Follow your healthcare professional's instructions and never alter the dose of CERTICAN on your own. CERTICAN is for oral use only.
- You should be advised that any change of cyclosporine (NEORAL) should be made cautiously and only under physician supervision as it may result in the need for a change in your CERTICAN dosage.

Usual dose:

Take 0.75 mg twice daily (12 hours apart) with your prescribed dose of cyclosporine and corticosteroid.

Your healthcare professional will adjust your maintenance dose as needed.

Overdose:

If you think you, or a person you are caring for, have taken too much CERTICAN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget to take CERTICAN, take it as soon as you remember, then continue to take it at the usual times. If it is almost time for your next dose, skip your missed dose. Never take two doses at the same time. Ask your healthcare professional for advice.

Possible side effects from using CERTICAN:

Like all medicines, CERTICAN can have side effects. However, since it is taken in combination with other medicines, the side effects cannot always be directly attributed with certainty to CERTICAN itself.

These are not all the possible side effects you may have when taking CERTICAN. If you experience any side effects not listed here, tell your healthcare professional.

The most common (incidence greater than 30%) adverse events observed in CERTICAN clinical studies are: constipation, nausea, anemia, peripheral edema (e.g. swelling of extremities such as hands or feet), infections and high blood pressure.

Very common side effects:

These side effects may affect between 10 or more in every 100 patients

- headache
- insomnia
- anxiety
- bump or bulge (hernia) at the site of surgery

Common side effects:

These side effects may affect between 1 and 10 in every 100 patients

- urinary tract infections
- general pain
- pain in the ear, nose or throat
- tremor
- cough
- acne
- impaired healing of general wounds
- mouth sores

Uncommon side effects:

These side effects may affect between 1 and 10 in every 1,000 patients

- rash
- muscle pain

There may be side effects that you are not aware of, such as abnormal results of laboratory tests, including tests of kidney function. Your doctor will therefore perform blood tests to monitor any changes. If you notice any side effects not mentioned in this leaflet or are concerned about those listed, please inform your doctor.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
High blood levels of lipids / cholesterol		✓	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		✓	
Anemia (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		✓	
Common			
Diarrhea, nausea, vomiting		✓	
Abdominal/general pain (can be a sign of ovarian cyst): Pelvic pain, painful intercourse, abdominal bloating or swelling, pain during bowl movements		✓	
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages		✓	
Pericardial effusion (the accumulation of fluid around the heart): sharp, piercing chest pain over the centre or left side of the chest which is more intense when breathing in, shortness of breath, palpitations, fever, fatigue, weakness or feeling sick, cough, swelling in the abdomen or leg		✓	
Lung Problems (worsening of lung symptoms): persistent cough, painful or difficult breathing, shortness of breath, cyanosis (blueish skin or fingernails), chest pain, fatigue, loss of appetite, unintentional weight loss		✓	
Leukopenia (decreased white blood cells): infections, fatigue,		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
fever, aches, pains and flu-like symptoms			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.		✓	
Increased risk of infection, abnormal healing of surgical wounds		✓	
Pancytopenia (decreased red and white blood cells and platelets): low red blood cell count: paleness of the skin, fatigue, rapid heart rate, shortness of breath; low white blood cell count: fever, and symptoms of infection such as cough; low platelet count: bruising easily and heavy bleeding		✓	
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, loss of appetite, tenderness when touching the abdomen		✓	
Diabetes: excessive thirst, excessive urination, excessive eating, unexplained weight loss, poor wound healing, infections		✓	
Proteinuria (excess proteins in urine): swelling of the hands, feet, face		✓	
Impotence and male hypogonadism: difficulty getting and keeping an erection, changes in sexual desire or sexual activity, less energy, depression, infertility		✓	
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness, unexplained loss of appetite		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes (drowsiness, confusion, coma)		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store CERTICAN between 15-30°C (59-86°F) in the original package in order to protect from light and moisture.
- Keep CERTICAN out of the reach and sight of children.

If you want more information about CERTICAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the Novartis website [<http://www.novartis.ca>]; or by calling 1-800-363-8883.

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