

Consumer Medicine Information (CMI) summary

1. Why am I using everolimus?

Everocan contains the active ingredient everolimus. Everolimus is used to treat adult patients who have had kidney, heart or liver transplants.

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

2. What should I know before I use everolimus?

Do not use if you have ever had an allergic reaction to everolimus 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 everolimus?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with everolimus 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 everolimus?

Kidney and heart transplantations:

- The usual starting dose is 0.75 mg EVEROCAN twice daily, taken in the morning and in the evening together with cyclosporine.
- The first dose of EVEROCAN will be given as soon as possible after transplantation.

Liver transplantation:

- The general recommended daily dose is 1 mg EVEROCAN twice daily, taken in the morning and in the evening, together with tacrolimus.
- The first dose of EVEROCAN will be given approximately four weeks after transplantation.

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

5. What should I know while using everolimus?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using everolimus.• Keep all of your doctor's appointments so that your progress can be checked.• Make sure you use a highly effective contraceptive to prevent pregnancy during treatment with EVEROCAN. If you become pregnant while taking this medicine, tell your doctor immediately. |
| Things you should not do | <ul style="list-style-type: none">• Do not take EVEROCAN 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. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how EVEROCAN affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep the tablets in the original packet and foils until it is time to take them.• Follow the instructions in the carton on how to take care of your medicine properly. |

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

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.

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.

EVEROCAN

Active ingredient(s): EVEROLIMUS

Consumer Medicine Information (CMI)

This leaflet provides important information about using everolimus. **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 everolimus.**

Where to find information in this leaflet:

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

1. Why am I using everolimus?

Everocan contains the active ingredient everolimus. EVEROCAN 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. EVEROCAN 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. EVEROCAN 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.

2. What should I know before I use everolimus?

Warnings

- Do not use everolimus if you are allergic to:**
 - Everolimus, or 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.
- Always check the ingredients to make sure you can use this medicine.
- 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.

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.

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.
- Talk to your doctor if you are breastfeeding or intend to breastfeed.
- EVEROCAN is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.
- Tell your doctor if you are breastfeeding. Breastfeeding is not recommended while you are taking EVEROCAN. It is not known whether EVEROCAN passes into breast milk and could affect your baby.

- Tell your doctor if you are male and you want to father children. EVEROCAN 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.
- EVEROCAN may cause infertility in male or female patients.
- Medicines that suppress the immune system like EVEROCAN 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.
- EVEROCAN 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 EVEROCAN.

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 and EVEROCAN may interfere with each other. These include:

- Immunosuppressive medicines other than cyclosporine 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 heartbeat.
- 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, an herbal product used to treat depression and other conditions.

Such medicines may be affected by EVEROCAN 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 EVEROCAN.

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

4. How do I use everolimus?

How much to take / use

Kidney and heart transplantations:

- The usual starting dose is 0.75 mg EVEROCAN twice daily, taken in the morning and in the evening together with cyclosporine.
- The first dose of EVEROCAN will be given as soon as possible after transplantation.

Liver transplantation:

- The general recommended daily dose is 1 mg EVEROCAN twice daily, taken in the morning and in the evening, together with tacrolimus.
- The first dose of EVEROCAN will be given approximately four weeks after transplantation.
- Follow the instructions provided and use everolimus until your doctor tells you to stop.

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

When to take / use everolimus

- Always take EVEROCAN 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.
- EVEROLIMUS 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 EVEROCAN.

How to take it

- Swallow the tablets whole with a full glass of water.
- Do not crush or chew them.
- Do not take EVEROCAN 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 EVEROCAN as long as you have your transplanted organ, or until your doctor changes your immunosuppressive medication.

If you forget to use everolimus

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 use too much everolimus

If you think that you have used too much everolimus, 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 everolimus?

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

EVEROCAN 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 EVEROCAN, 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 EVEROCAN.

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

Things you must not do

Do not take EVEROCAN 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 EVEROCAN affects you.

If you go out in the sun, wear a hat, protective clothing and sunscreen. Do not use a sun lamp.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

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.

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 |
|--|--|
| Nosebleeds, acne, abdominal pain, nausea, vomiting, diarrhea, 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), 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, difficulty sleeping, anxiety, headache, fever, rash increased heart rate, breathlessness, ovarian cyst | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">• 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 | 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. |

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.

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 everolimus contains

| | |
|---|--|
| Active ingredient (main ingredient) | Everolimus |
| Other ingredients (inactive ingredients) | butylated hydroxytoluene lactose Monohydrate hypromellose lactose anhydrous crospovidone magnesium stearate |
| Potential allergens | |

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

What everolimus looks like

EVEROCAN 0.25 mg: White to off white, round shaped tablets debossed with "EVR" on one side and "25" on other side. (Aust R 335146).

EVEROCAN 0.5 mg: White to off white, round shaped tablets debossed with "EVR" on one side and "50" on other side. (Aust R 335141).

EVEROCAN 0.75 mg: White to off white, round shaped tablets debossed with "EVR" on one side and "75" on other side. (Aust R 335142).

EVEROCAN 1 mg: White to off white, round shaped tablets debossed with "EVR" on one side and "100" on other side. (blister pack: Aust R 335144). (bottle pack Aust R 335148)

Who distributes everolimus Pharmacor Pty Ltd.

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The Zenith, 821 Pacific Highway,
Chatswood, NSW, 2067,
Australia

www.pharmacor.com.au

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