

RAPAMUNE®

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 Rapamune?

Rapamune contains the active ingredient sirolimus. Rapamune belongs to a group of medicines called immunosuppressants. It is used to prevent your body from rejecting the transplanted kidney.

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

2. What should I know before I use Rapamune?

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

3. What if I am taking other medicines?

Some medicines may interfere with Rapamune and affect how it works. These include ciclosporin, antibiotics, antifungal medicines, medicines for high blood pressure or heart problems, epilepsy medicines, medicine for stomach ulcer or reflux, medicines to prevent nausea and vomiting, danazol, bromocriptine, letermovir, protease inhibitors, ACE inhibitors, cannabidiol or St. John's Wort. 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 Rapamune?

The usual starting dose is 6 mg after transplantation and then 2 mg once daily. You will also need to take medicines such as ciclosporin and corticosteroids. After 2 to 4 months, your doctor will start reducing the dose of ciclosporin you take and increasing your dose of Rapamune. Eventually your ciclosporin will be completely stopped. Your doctor will determine how much Rapamune you need to take.

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

5. What should I know while using Rapamune?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Rapamune.• Attend all doctor's appointments to monitor your condition.• Take any antibiotic medication for as long as your doctor prescribes them.
Things you should not do	<ul style="list-style-type: none">• Do not give Rapamune to anyone else even if they have the same condition as you.• Do not use Rapamune to treat any other complaints unless your doctor tells you to.• Do not stop taking Rapamune, or change the dosage, without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Keep Rapamune in its original container.• Store protected from light, in a refrigerator (2 to 8°C).• Once the bottle has been opened, keep the contents in the fridge and use within one month.• Discard syringe after one use only.• Keep Rapamune where children cannot reach it.

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

6. Are there any side effects?

Serious side effects may include signs of an allergy; signs of excessive fluid on the lungs; swelling of hands, feet, limbs, abdomen, or eyes; constant 'flu-like' symptoms; new or changes to lumps, spots or moles; signs of a blood disorder; signs that blood clots may have formed; signs of a disorder which may cause headache, confusion, seizures and visual loss or disturbance.

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.

RAPAMUNE® (rap-a-moon)

Active ingredient(s): sirolimus (sear-o-lime-us)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Rapamune?

Rapamune contains the active ingredient sirolimus.

Rapamune belongs to a group of medicines called immunosuppressants. It helps to control your body's immune system after you have received an organ transplant. It is used to prevent your body from rejecting the transplanted kidney.

Rapamune is not recommended for patients who have received liver or lung transplants.

Your doctor may have prescribed Rapamune for another reason. Ask your doctor if you have any questions about why Rapamune has been prescribed for you.

Rapamune is not recommended for use in children, as there is limited information available on its effects in children.

Rapamune is not habit-forming.

2. What should I know before I use Rapamune?

Warnings

Do not take Rapamune if you have an allergy to sirolimus or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest, swelling of the face, lips, tongue or other parts of the body, rash, itching, hives or flushed red skin, dizziness or light-headedness.

If you are not sure whether this applies to you, check with your doctor.

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

Check with your doctor if you:

- have or have had any medical conditions, especially the following:
 - liver problems or a disease which may have affected your liver
 - high fat levels in the blood

- a condition called rhabdomyolysis, which may cause a variety of symptoms including muscle weakness and tenderness and temporary paralysis.

If you have not told your doctor about any of the above, tell them before you start taking Rapamune.

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.

Like most immunosuppressive medicines, Rapamune is not recommended for use during pregnancy.

If you are a woman, before starting Rapamune you must be using effective contraception methods and you must continue contraception for 12 weeks after treatment has stopped. If you are unsure, or think you may have become pregnant, talk to your doctor or pharmacist. Discuss contraceptive options with your doctor.

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

Like most immunosuppressive medicines, Rapamune is not recommended while you are breastfeeding. It is not known whether Rapamune passes into breast milk. Ask your doctor or pharmacist for advice before breastfeeding your baby.

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 Rapamune and affect how it works.

These include:

- ciclosporin used to prevent transplant rejection
- antibiotics such as rifampicin, clarithromycin, erythromycin and rifabutin
- antifungal medicines such as ketoconazole, clotrimazole, fluconazole, voriconazole and itraconazole
- medicines for high blood pressure or heart problems such as diltiazem, and verapamil
- epilepsy medicines such as carbamazepine, phenobarbitone and phenytoin
- 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
- letermovir which is used to help prevent sickness from CMV (cytomegalovirus) in adults who have recently had a bone marrow transplant
- protease inhibitors such as ritonavir, boceprevir, telaprevir and indinavir, which are used to treat HIV/AIDS

- ACE inhibitors such as perindopril and ramipril which are used to treat high blood pressure
- cannabidiol which is used to treat epilepsy and chronic pain, and to improve symptoms related to muscle stiffness and spasms in multiple sclerosis
- St. John's wort.

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

4. How do I use Rapamune?

Rapamune is for oral use only.

Always take the medicine exactly as your doctor tells you.

How much to take

Your doctor will decide exactly what dose of Rapamune you must take and how often to take it.

Follow your doctor's instructions exactly and never change the dose yourself. Do not stop taking your medicine unless your doctor tells you to.

The usual starting dose is 6 mg after transplantation and then 2 mg once daily. You will also need to take medicines such as ciclosporin and corticosteroids.

After 2 to 4 months, your doctor will start reducing the dose of ciclosporin you take and increasing your dose of Rapamune. Eventually your ciclosporin will be completely stopped. Your doctor will determine how much Rapamune you need to take.

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

These directions may differ from the information contained in this leaflet.

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

How to take Rapamune

Take Rapamune consistently, either with or without food.

Do not take Rapamune with grapefruit juice.

Follow these instructions to prepare Rapamune for use:

1. Remove the safety cap from the bottle by squeezing the tabs on the cap and twisting counter-clockwise. The first time you use a bottle of Rapamune Oral Solution, insert the syringe adaptor into the bottle until it is flush with the top of the bottle. Do not attempt to remove the syringe adaptor from the bottle once inserted.

2. Use a new dosing syringe for each dose of Rapamune Oral Solution. With the plunger fully depressed, insert one of the dosing syringes into the opening in the adaptor.

3. Withdraw the exact amount of Rapamune as prescribed by your doctor by gently pulling out the plunger of the dosing syringe until the level of the oral solution is even with the mark on the dosing syringe for the prescribed dose. The bottle should remain in an upright position when withdrawing the solution. If bubbles form in the dosing syringe during withdrawal, empty the Rapamune solution back into the bottle and repeat the withdrawal procedure.

4. You may have been instructed to take your Rapamune oral solution at a particular time of day. If it is necessary to carry your medication with you, place a cap securely on the dosing

syringe - the cap should snap into place. Then place the capped dosing syringe in the carrying case provided. Once in the syringe the medication may be kept at room temperature or refrigerated and used within 24 hours.

5. Empty the contents of the dosing syringe into a glass or plastic cup containing at least 60 mL of water or orange juice. Stir quickly for one minute and drink at once.

6. When mixed with water or orange juice Rapamune produces a white to off-white mixture.

7. Refill the glass or plastic cup with at least 120 mL of water or orange juice, stir quickly, and drink at once.

Do NOT use any liquids other than water or orange juice for dilution. Only use a glass or plastic cup to dilute Rapamune and drink the preparation immediately after dilution. Use the dosing syringe and syringe cap once only and then discard.

Note:

When refrigerated the solution in the bottle may separate or appear hazy. If this occurs, bring your Rapamune oral solution to room temperature and shake gently. The presence of a haze does not affect the quality of Rapamune.

When to take Rapamune

Take Rapamune once a day at about the same time each day.

Taking Rapamune at the same time each day will have the best effect. It will also help you remember when to take it.

If you are also taking ciclosporin, then you must take Rapamune 4 hours after your ciclosporin dose.

How long to take Rapamune

You will need to take Rapamune for the rest of your life, or until your doctor decides to change your immunosuppressive medication.

If you forget to take Rapamune

If it is almost time for your next dose (within 4 hours), 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 and always take Rapamune and ciclosporin approximately 4 hours apart.

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 Rapamune

If you think that you have taken too much Rapamune, 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.

If you take too much Rapamune, your heart may start beating abnormally.

5. What should I know while using Rapamune?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Rapamune.

Attend all doctor's appointments to monitor your condition.

Your doctor needs to closely monitor the level of Rapamune found in your blood to make sure the dose you are taking is best for your condition.

Take any antibiotic medication for as long as your doctor prescribes them.

Taking antibiotics helps prevent getting an infection.

Tell your doctor you are taking Rapamune if you also want to be vaccinated.

Rapamune may affect your response to vaccination.

Things you should not do

Do not give Rapamune to anyone else even if they have the same condition as you.

Do not use Rapamune to treat any other complaints unless your doctor tells you to.

Do not stop taking Rapamune, or change the dosage, without checking with your doctor.

Kidney transplant patients need to remain on immunosuppressive medication indefinitely.

Driving or using machines

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

Things to be careful of

Limit your exposure to sunlight and UV light by wearing protective clothing and using a sunscreen with a high protection factor.

Immunosuppressive medicines such as Rapamune may increase the risk of developing cancer of the lymph glands and skin.

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

This may be a sign of cancer. Immunosuppressant medicines, including Rapamune, may increase the risk of developing certain cancers, including skin cancer and lymphoma (cancer of the lymphatic system).

Looking after your medicine

Keep Rapamune in its original container. Store protected from light, in a refrigerator (2 to 8°C). Once the bottle has been opened, keep the contents in the fridge and use within one month. Discard syringe after one use only.

Heat can destroy some medicines.

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
<ul style="list-style-type: none"> • burning sensation on urination or increased urgency to urinate • increased thirst and hunger • fluid filled swelling on the skin • abnormal wound healing • fast heartbeat • pain • diarrhoea • mouth ulcers and cold sores • nosebleed • pneumonia • acne • rash • fever • headache • constipation • nausea • symptoms of ovarian cyst, such as discomfort around the pelvis or abdomen or pain or pressure upon urination or bowel movements • changes in menstrual bleeding patterns. 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body shortness of breath, wheezing or troubled breathing • signs of excessive fluid on the lungs such as coughing, difficulty breathing and wheezing • swelling of hands, feet, limbs or abdomen or puffiness or swelling around the eyes due to fluid retention • constant 'flu-like' symptoms such as fever, chills, sore throat, aching joints, swollen glands, cough, or any other signs of infection such as infection of a cut or scratch. Immunosuppressive drugs may 	<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>also increase the risk of getting an infection</p> <ul style="list-style-type: none"> new lumps, spots or moles, or changes to existing lumps, spots or moles, anywhere on your body. It is important to have these checked by a doctor as soon as possible signs of a blood disorder such as tiredness, headaches, being short of breath when exercising, dizziness, paleness, nose bleeds, unusual bleeding or bruising signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood signs of a disorder which may cause headache, confusion, seizures and visual loss or disturbances. 	

<ul style="list-style-type: none"> ethanol soya fatty acids ascorbyl palmitate.
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Do not take this medicine if you are allergic to any of these ingredients.

Rapamune does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Rapamune looks like

Rapamune oral solution is a pale yellow to yellow solution.

Rapamune oral solution is supplied in 60 mL amber glass bottles.

AUST R 73921

Who distributes Rapamune

Pfizer Australia Pty Ltd

Level 17, 151 Clarence Street

SYDNEY NSW 2000

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2023.

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Unwanted side effects that you may not be aware of whilst taking Rapamune include an increase in blood pressure and changes in the levels of red or white blood cells or substances carried in your blood (e.g. fat, cholesterol, protein, potassium or liver enzymes). During treatment your doctor may do blood tests to measure these changes.

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 Rapamune contains

Active ingredient (main ingredient)	sirolimus
Other ingredients (inactive ingredients)	Polysorbate 80 Phosal 50 PG Phosal 50 PG contains: <ul style="list-style-type: none"> phosphatidylcholine propylene glycol mono- and di-glycerides