

RAPAMUNE®

Sirolimus Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rapamune. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Rapamune against the benefits this medicine is expected to 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 Rapamune is used for

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.

This medicine is available only with a doctor's prescription.

Rapamune is not habit-forming.

Before you take Rapamune

When you must not take Rapamune

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.

Do not take Rapamune if the packaging is torn or shows signs of tampering.

Do not take Rapamune after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking Rapamune, contact your doctor.

Before you start to take Rapamune

Tell your doctor if:

1. You have any allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. 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.

3. You are breast-feeding or plan to breast-feed.

Like most immunosuppressive medicines, Rapamune is not recommended while you are breast-feeding. It is not

known whether Rapamune passes into breast milk. Ask your doctor or pharmacist for advice before breast-feeding your baby.

4. 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.

Taking other medicines

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

Some medicines and Rapamune may interfere with each other. 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.

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

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

How to take 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 pack, ask your doctor or pharmacist for help.

How to take Rapamune

Swallow Rapamune tablets with a glass of water or orange juice. Do not take Rapamune tablets with grapefruit juice.

Rapamune tablets must be taken whole.

If you crush, split or chew the tablets you may not get the correct dose.

If you have problems with swallowing the tablets whole discuss with your doctor whether Rapamune Oral solution would be better for you.

Take Rapamune consistently, either with or without food.

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel. 13 11 26 in Australia or 0800 764 766 in New Zealand), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Rapamune. Do this even if there

are no signs of discomfort or poisoning. Take the labelled medicine pack with you, even if it is empty.

You may need urgent medical attention. If you take too much Rapamune, your heart may start beating abnormally.

While you are using Rapamune

Things you must 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.

Things you must 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.

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).

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Rapamune. Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Side Effects

Check with your doctor as soon as possible if you have any problems while taking Rapamune, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

If you get any side effects, do not stop taking Rapamune without first talking to your doctor.

Rapamune helps most people with kidney transplants but it may have unwanted side effects. However, since Rapamune is often taken in combination with other medicines, Rapamune may not have necessarily caused the side effects.

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

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following. These may be very serious side effects. You may need urgent medical attention or hospitalisation:

- 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. Immuno-suppressive drugs may also increase the risk of getting an infection
- 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.

Tell your doctor if you notice any of the following side effects:

- burning sensation on urination or increased urgency to urinate
- increased thirst and hunger
- fluid filled swelling on the skin
- abnormal wound healing
- fast heart beat
- pain
- diarrhoea
- mouth ulcers and cold sores
- nose bleed
- 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.

These are common side effects of Rapamune.

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

Rapamune may affect your response to vaccination.

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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Rapamune

Storage

Keep Rapamune tablets in their blister pack until it is time to take them.

If you take the tablets out of their blister pack they may not last as well.

Keep Rapamune tablets in a cool, dry place where the temperature stays below 25°C.

Do not store Rapamune tablets or any other medicine in the bathroom or near a sink. Do not leave Rapamune in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Rapamune where 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 Rapamune or the tablets have passed their expiry date, ask your pharmacist what to do with the left over tablets.

Product description

What it looks like

Rapamune 0.5 mg tablets are tan, triangular-shaped, sugar-coated tablets branded with red ink.

Rapamune 0.5 mg tablets are supplied in cartons of 100 tablets (10 blisters x 10 tablets each).

Rapamune 1 mg tablets are white, triangular-shaped, sugar-coated tablets branded with red ink.

Rapamune 1 mg tablets are supplied in cartons of 100 tablets (10 blisters x 10 tablets each).

Rapamune 2 mg tablets are yellow, triangular-shaped, sugar-coated tablets branded with red ink.

Rapamune 2 mg tablets are supplied in cartons of 100 tablets (10 blisters x 10 tablets each).

Ingredients

Each Rapamune tablet contains the active ingredient, sirolimus.

The inactive ingredients are:

- Lactose monohydrate
- Macrogol 8000
- Magnesium stearate
- Purified talc
- Macrogol 20000
- Glyceryl mono-oleate
- Shellac
- Calcium sulfate

- Microcrystalline cellulose
- Sucrose
- Titanium dioxide
- dl-alpha-tocopherol
- Poloxamer
- Povidone
- Carnauba wax
- Opacode monogramming ink S-1-15095 RED

Rapamune 0.5 mg and Rapamune 2 mg tablets also contain the colouring agents iron oxide yellow CI 77492, iron oxide black CI 77499 and iron oxide red CI 77491.

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

Supplier

Rapamune is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number 1800 675 229

www.pfizermedinfo.com.au

Australian Registration Numbers:

Rapamune 0.5 mg tablets: AUST R 169305

Rapamune 1 mg tablets: AUST R 125629

Rapamune 2 mg tablets: AUST R 125630

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