

RAPAMUNE®

Sirolimus (1 mg)

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What Rapamune is used for

Rapamune is a medicine used to prevent rejection (anti-rejection medicine) in people who have received a kidney transplant. Rejection is when your body's immune system recognizes the new organ as a "foreign" threat and attacks it.

You will be determined if you have a low to moderate immunological risk or high immunological risk.

If you belong to low to moderate immunological risk, you will be asked to take Rapamune initially in a regimen with cyclosporine and corticosteroids.

Cyclosporine will be withdrawn 2 to 4 months after transplantation, and the Rapamune dose will be increased to reach recommended blood concentrations.

If you belong to high immunologic risk (defined as Black transplant recipients and/or repeat kidney transplant recipients who lost a previous transplant for immunologic reason and/or individuals with high-panel reactive antibodies (PRA; peak PRA level > 80%), you will be asked to take Rapamune in combination with tacrolimus and corticosteroids or cyclosporine and corticosteroids for the first year following transplantation. Whether these

combinations are safe and effective in high-risk renal transplant patients have not been studied beyond one year. Therefore, after the first year following transplantation, any adjustments to these regimens will be considered on the basis of your clinical status.

How Rapamune works

Rapamune inhibits the activation and increase in the number or amount of a type of white blood cell called T-lymphocyte. Your body produces T-lymphocytes to fight against infection or foreign substances which have entered the body. Rapamune also inhibits antibody production. Antibody is a blood protein produced in response to a foreign substance. This prevents your body from rejecting the transplanted kidney.

Before you use Rapamune

- When you must not use it

Do not take Rapamune if you are allergic to sirolimus or to any other ingredients in Rapamune.

Rapamune has not been shown to be safe and effective in people who have had liver or lung transplants. Serious complications and death may happen in people who take Rapamune after a liver or lung transplant. You should not take Rapamune if you have had a liver or lung transplant without talking to your doctor.

Pregnancy and lactation

Do not take Rapamune if you are pregnant, trying to get pregnant or think you may be pregnant.

You must use an effective method of birth control during treatment and for 12 weeks after you stop treatment with Rapamune. Tell your doctor right away if you become pregnant or think you are pregnant while taking Rapamune. Rapamune should only be

used if your doctor has ascertained that its benefits outweigh its risk to your baby.

It is not known whether Rapamune passes into breast milk. You and your doctor should decide if you will take Rapamune or breastfeed. You should not do both.

- Before you start to use it

Before taking Rapamune, tell your doctor if you:

- have liver problems
- have skin cancer or it runs in your family
- have high cholesterol or triglycerides (fat in your blood)
- have impaired or delayed wound healing
- have kidney problem

- Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Using Rapamune with certain medicines may affect each other causing serious side effects.

Rapamune may affect the way other medicines work, and other medicines may affect how Rapamune works.

Especially tell your doctor if you take the following type of medicine

- a medicine to lower your cholesterol or triglycerides
- cyclosporine, or other medicines that suppress the immune system
- an antibiotic (clarithromycin, erythromycin, telithromycin, troleandomycin, rifabutin, rifampicin, rifapentine)

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grapefruit juice.

- Things to be careful of

Driving and using machines

No formal studies have been carried out to study the effects of Rapamune on the ability to drive and use machines.

Side Effects

Like all medicines, Rapamune can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common side effects may affect more than 1 in 10 people:

- high blood pressure
- pain (including stomach and joint pain)
- diarrhea
- headache
- fever
- infections (Pneumonia, fungal infection, viral infection, bacterial infection, herpes simplex, urinary tract infection)
- low red blood cell count (anemia)
- nausea
- low platelet count (cells that help blood to clot)
- increased heart rate
- low white blood cell count
- constipation (hard stools)
- rash
- pimples
- menstrual disorders
- abnormal high glucose levels
- raised lipids
- low potassium and phosphate
- swelling of the extremities
- diabetes mellitus
- accumulation of lymphatic fluid in the body
- protein in the urine
- impaired healing
- abnormal liver function test

- increased blood creatinine
- increased blood lactate dehydrogenase

Common side effects may affect up to 1 in 10 people:

- inflammation of mouth and lips
- collection of fluid in the space within the heart (pericardial effusion)
- inflammation of pancreas gland
- fluid collection in the abdomen
- allergic reactions
- severe infections (bacterial and viral)
- breakdown of bones
- skin cancer
- cysts in the ovary
- blockage in the lung vessels
- fluid in the lung space
- bleeding through the nose
- blockage in the leg vessels
- inflammation of the lungs
- hemolytic-uremic syndrome (which is a combination of anemia, kidney failure and low platelet count)

Uncommon side effects may affect up to 1 in 100 people:

- Cancer of the lymph tissue (lymphoma/post-transplant lymphoproliferative disorder), combined lowering of red blood cells, white blood cells and blood platelets
- Bleeding from the lung
- Nephrotic syndrome (a group of symptoms that indicate your kidneys are not working properly including protein in the urine)
- Scarring in the kidney that may reduce kidney function (Focal segmental glomerulosclerosis)
- Too much fluid collecting in the tissues due to irregular lymph function (lymphoedema)
- Low blood platelets, with or without rash (thrombocytopenic purpura)
- Serious allergic reactions that can cause peeling of the skin
- Tuberculosis

- Epstein-Barr virus infection

Rare side effects may affect up to 1 in 1,000 people:

- Protein build-up in the air sacs of the lungs that may interfere with breathing (alveolar proteinosis).
- Serious allergic reactions that can affect blood vessels (hypersensitivity vasculitis).

Not known side effects: frequency cannot be estimated from the available data:

- Posterior reversible encephalopathy syndrome (PRES), a serious nervous system syndrome that has the following symptoms: headache, nausea, vomiting, confusion, seizures, and visual loss. Should any of these occur together, please contact your physician.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These may not be all of the possible side effects of Rapamune. For more information ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Rapamune

- Storage

Rapamune Tablets should be stored below 30°C. Use cartons to protect blister cards and strips from light. Dispense in a tight, light-resistant container as defined in the USP.

Keep out of the reach and sight of children.

- Disposal

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Medicines should not be disposed
via wastewater or household waste.

Ask your pharmacist how to
dispose of medicines no longer
required. These measures will help
to protect the environment.

Date of Revision

25/03/2025

Serial Number

NPRA (R1/4) 25032025/053

PLD-RAPAMUNE-0325

Product Description

- What it looks like

Rapamune Tablets are available as
follows:

1 mg, white, triangular-shaped
sugar coated tablets branded
“RAPAMUNE 1 mg” in red ink.

Rapamune is supplied as follows:

Bottle of 100 tablets.

Blister in cartons of 30's

Not all pack size may be marketed.

- Ingredients

- Active ingredient(s)
Sirolimus

- Inactive ingredients
Lactose monohydrate,
Polyethylene glycol 8000
powdered,
Magnesium stearate,
Talc.

- MAL number:

MAL20032403ARZ

Manufacturer

Pfizer Ireland Pharmaceuticals
Unlimited Company,
Little Connell, Newbridge, Co.
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Product Registration Holder

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