PATIENT & CAREGIVER EDUCATION

Sirolimus

This information from Lexicomp® explains what you need to know about this medication, including what it’s used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US
Rapamune

Brand Names: Canada
Rapamune

Warning

- This drug may raise the chance of very bad and sometimes deadly infections. Talk with the doctor.

- Call your doctor right away if you have any signs of infection like fever, chills, flu-like signs, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or a wound that will not heal.

- This drug may raise the chance of getting cancer like lymphoma or skin cancer. Call your doctor right away if you have a change in color or size of a mole, a skin lump or growth, a big weight loss, night sweats, or swollen glands.
• This drug is not for use in people who have had liver or lung transplants. Very bad and sometimes deadly problems have happened in these people. Talk with the doctor.

**What is this drug used for?**

• It is used after a kidney transplant to keep the body from rejecting the kidney.
• It is used to treat a lung disease called lymphangioleiomyomatosis (LAM).
• It may be given to you for other reasons. Talk with the doctor.

**What do I need to tell my doctor BEFORE I take this drug?**

• If you have an allergy to sirolimus or any other part of this drug.
• If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
• If you are taking any of these drugs: Clarithromycin, erythromycin, itraconazole, ketoconazole, rifabutin, rifampin, telithromycin, or voriconazole.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health
problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

**What are some things I need to know or do while I take this drug?**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- This drug may cause high cholesterol and triglyceride levels. Talk with the doctor.
- High blood sugar has happened with this drug. This includes diabetes that is new or worse.
- Check your blood sugar as you have been told by your doctor.
- Tell your doctor if you have signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
• You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.

• The chance of skin cancer may be raised. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.

• Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.

• Avoid grapefruit and grapefruit juice.

• This drug may affect how wounds heal. Sometimes, people with wound healing problems have needed surgery. Call your doctor right away if you have a wound that is red, warm, painful, or swollen. Call your doctor right away if your wound opens up or if there is blood, fluid, or pus in a wound.

• Some people treated with this drug have had very bad kidney problems caused by a certain viral infection (BK virus). In people who have had a kidney transplant, BK virus infection may cause loss of the kidney. Call your doctor right away if you have signs of kidney problems like change in the amount of urine passed, difficulty or pain when passing urine, or blood in the urine.

• Very bad and sometimes deadly blood problems like thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS) have happened with this drug in some people. Call your doctor right away if you feel very tired or weak or have any bruising or bleeding; dark urine or yellow
skin or eyes; pale skin; change in the amount of urine passed; change in eyesight; change in strength on 1 side is greater than the other, trouble speaking or thinking, or change in balance; or fever.

- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- Women must use birth control while taking this drug and for some time after the last dose. Ask your doctor how long to use birth control. If you get pregnant, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

**What are some side effects that I need to call my doctor about right away?**

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.

- Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal.

- A fast heartbeat.

- Feeling very tired or weak.

- Swelling in the arms or legs.

- Any unexplained bruising or bleeding.

- Period (menstrual) changes.

- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

- Some people have had lung problems with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of lung problems like shortness of breath or other trouble breathing, cough that is new or worse, or fever.

- A very bad brain problem called progressive multifocal leukoencephalopathy (PML) has happened with this drug. It may cause disability or can be deadly. Tell your doctor right away if you have signs like confusion, memory problems, low mood (depression), change in the way you act, change in strength on 1 side is greater than the other, trouble speaking or thinking, change in balance, or change in
eyesight.

- Liver problems have rarely happened with this drug. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

**What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Stomach pain.
- Diarrhea or constipation.
- Upset stomach.
- Joint pain.
- Pimples (acne).
- Dizziness.
- Nose or throat irritation.
- Mouth irritation or mouth sores.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.
You may report side effects to your national health agency.

How is this drug best taken?
Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with or without food but take the same way each time. Always take with food or always take on an empty stomach.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you are taking cyclosporine, take it at least 4 hours before taking this drug.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Have your urine checked as you have been told by your doctor.

Tablets:

- Swallow whole. Do not chew, break, or crush.
- If you have trouble swallowing, talk with your doctor.

Oral solution:

- Put 1/4 cup of water or orange juice into a glass or plastic container. Do not mix with other liquids.
- Measure this drug in the oral dose syringe. Empty drug from
Syringe into cup. Mix well and drink.

- Fill container again with $\frac{1}{2}$ cup of water or orange juice. Mix well and drink.

- After mixing, take your dose right away. Do not store for future use.

- Throw syringe away after use. Do not use the same syringe more than one time.

- If you get this drug on the skin, wash it off right away with soap and water.

- If this drug gets in the eyes, rinse with cool water.

**What do I do if I miss a dose?**

- Take a missed dose as soon as you think about it.

- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.

- Do not take 2 doses at the same time or extra doses.

**How do I store and/or throw out this drug?**

**Tablets:**

- Store at room temperature.

- Store in a dry place. Do not store in a bathroom.

- Do not take this drug out of the blister pack until you are ready to take it. Take this drug right away after opening the blister pack. Do not store the removed drug for future use.

**Oral solution:**
• Store in a refrigerator. Do not freeze.
• After opening, throw away any part not used after 1 month.
• This drug may also be stored at room temperature. If stored at room temperature, throw away any part not used after 15 days.
• Liquid (solution) may look hazy when refrigerated. Bring to room temperature and shake gently until haze goes away.
• Liquid (solution) in a syringe may be stored at room temperature or in a refrigerator for up to 24 hours.

**All products:**

• Protect from light.
• Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

**General drug facts**

• If your symptoms or health problems do not get better or if they become worse, call your doctor.
• Do not share your drugs with others and do not take anyone else’s drugs.
• Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

• If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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