UPMC | HILLMAN CANCER CENTER

Sirolimus (Rapamune)

About This Medicine

SIROLIMUS (sir OH li mus) prevents the body from rejecting an organ transplant. It works by lowering the body's immune system response. This helps the body accept the donor organ. It is also used to treat lymphangioleiomyomatosis (LAM), a condition that affects the lungs, kidneys, and lymph nodes. It belongs to a group of medications called immunosuppressants. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Nausea
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Swelling of your legs, ankles and/or feet
- Inflammation of the nasal passages and throat
- Increased cholesterol levels
- Feeling dizzy
- Headache
- Muscle pain/aching
- Pain in your chest
- Upper respiratory tract infection
- Pimple like rash

Note: *Each of the side effects above was reported in 20% or greater of people treated with sirolimus. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.*

Warnings and Precautions

- This medicine may raise your risk of getting another cancer, such as lymphoma and skin cancer.

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- Risk of severe and life-threatening infections
- Some viruses can be reactivated and affect your kidneys and/or your central nervous system (brain and spinal cord) and can be life-threatening. You could feel extreme tiredness, agitation, confusion, have trouble understanding or speaking, trouble thinking and/or memory loss, trouble walking, eyesight changes, numbness or lack of strength to your arms, legs, or seizures. **If you start to have any of these symptoms let your care team know right away.**
- Allergic reactions, including anaphylaxis are rare but may happen in some people. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**
- Slow wound healing
- Risk of angioedema (if you are also taking a type of medicine called an ACE inhibitor). Symptoms may be swelling of the face, feeling like your tongue or throat are swelling, and trouble breathing.
- Severe swelling of the hands, feet, or any other part of the body. Fluid may build up around your lungs and/or heart.
- Increases in your cholesterol or triglyceride levels which may require changes in diet, exercise, or the addition of medicine.
- Increased protein in your urine, which can affect how your kidneys work and changes in your kidney function, which can cause kidney failure
- Inflammation (swelling) and/or scarring of the lungs. You may have a cough and/or trouble breathing.

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.*

Important Information

- Talk to your care team before receiving any vaccinations during your treatment. Some vaccinations are not recommended while receiving sirolimus.
- Sirolimus may cause slow wound healing. If you must have emergency surgery or have an accident that results in a wound, tell the care team that you are on sirolimus.

How to Take Your Medicine

- **Tablets only**: Swallow the medicine whole with or without food at the same time each day. Do not crush, chew or split tablets.
- Take the medicine at the same time each day. Take each dose the same way, either with or without food. This helps keep the levels of sirolimus in your blood more stable.
- **Solution only**: Take the syringe and withdraw the prescribed amount of medicine from the bottle. Empty the syringe into a glass or plastic container containing at least 2 ounces (1/4 cup) of water or orange juice. No other liquids, including grapefruit juice, should be used. Stir well for one minute and drink right away. Refill the container with at least 4 more ounces (1/2 cup) of water or orange juice, stir well and drink right away.

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- Take the medicine at the same time each day. Take each dose the same way, either with or without food. This helps keep the levels of sirolimus in your blood more stable.
- Your care team may change your dose based on the result of blood work.
- **Missed dose**: If you vomit or miss a dose, contact your care team. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage**: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling**: Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- If you get any of the contents of the solution on your skin or in your eyes, you should wash the area of the skin well with soap and water right away. Wash your eyes with flowing water and call your care team. Call your care team if you get a skin reaction.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage**: **Tablet only**: Store the sirolimus blister cards and strips at room temperature between 68°F to 77°F (20°C to 25°C) and in the original carton to protect from light. If your sirolimus is dispensed in a bottle, keep it in the original container with lid tightly closed. Protect from light. Keep out of the reach of children and pets.
- **Solution only**: Store the sirolimus solution in the original bottle in the refrigerator, between 36°F to 46°F (2°C to 8°C). Protect from light. Opened bottles should be used within 30 days. It is safe to keep the solution at room temperature up to 77°F (25°C) for not more than 15 days. The solution can become hazy once refrigerated. If this happens, bring the solution to room temperature, and shake bottle gently until no longer hazy. Use any diluted solution right away. Keep out of the reach of children and pets.
- **Disposal of unused medicine**: Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine

Treating Side Effects

- Get regular exercise, with your care team ’s approval. If you feel too tired to exercise vigorously, try taking a short walk.
- If you are dizzy, get up slowly after sitting or lying.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea.

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- To help with nausea, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Avoid sun exposure and apply sunscreen routinely when outdoors. Cover up when you are out in the sun. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of sirolimus in your body which could make side effects worse.
- Check with your care team or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with sirolimus. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John’s Wort while taking sirolimus as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Extreme tiredness, agitation or confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Trouble walking
- Trouble understanding or speaking
- Trouble thinking and/or memory loss
- Headache that does not go away

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- Blurry vision or other changes in eyesight
- Numbness of lack of strength in your arms, legs, face, or body
- Feeling dizzy or lightheaded
- Weakness that interferes with your daily activities
- Wheezing and/or trouble breathing
- Dry cough
- Coughing up yellow, green, or bloody mucus
- Chest pain, especially when you lean forward or take deep breaths
- Pain in your abdomen
- Pain that does not go away, or is not relieved by prescribed medicines
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles and/or feet
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Foamy or bubbly-looking urine
- Decreased or very dark urine
- A new rash or a rash that is not relieved by prescribed medicines
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of angioedema: swelling of the face, feeling like your tongue or throat are swelling, and trouble breathing.

Reproduction Warnings

- **Pregnancy warning**: This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 12 weeks after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning**: Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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