

UPMC | HILLMAN CANCER CENTER

Sirolimus (Rapamune®)

About This Drug

Sirolimus is used to decrease the risk of rejection of a transplanted organ. It is also used in a rare lung disease and to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in red blood cells and platelets. This may make you feel more tired and raise your risk of bleeding.
- Chest pain
- 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
- Fever
- Inflammation of the nasal passages and throat
- Urinary tract infection
- Increased cholesterol and triglyceride levels
- Feeling dizzy
- Headache
- Pain
- Joint, muscle and bone pain
- Changes in your kidney function
- Upper respiratory infection
- Pimple like rash
- High blood pressure

Note: Each of the side effects above was reported in 20% or greater of patients treated with sirolimus. Not all possible side effects are included above.

Warnings and Precautions

- This drug may raise your risk of getting a second cancer, such as lymphoma and skin cancer
- Severe infections, including viral, bacterial and fungal, which can be life-threatening
- Some viruses can be reactivated and affect your kidneys and/or your central nervous system (brain and spinal cord). You could feel extreme tiredness, confusion, trouble understanding or speaking, difficulty walking, numbness or lack of strength to your arms, legs, face, or body, or other problems.
- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug 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 drug. You should get urgent medical treatment.
- Slow wound healing
- Severe swelling of your legs, ankles and/or feet, or fluid build-up around your lungs, heart or elsewhere
- Increased protein in your urine, which can affect how your kidneys work
- Scarring of the lungs that causes stiffness in the lungs or inflammation (swelling) which makes breathing difficult.

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 doctor before receiving any vaccinations during your treatment. Some vaccinations are not recommended while receiving sirolimus.

How to Take Your Medication

- **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 of water or orange juice. No other liquids, including grapefruit juice should be used. Stir well and drink right away. Refill the container with at least 4 more ounces of water or orange juice, stir well and drink right away. The solution can become hazy once refrigerated. If this happens, bring the solution to room temperature, and shake bottle until no longer hazy.
- 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 doctor may change your dose based on the result of blood work**
- **Missed dose:** If you vomit or miss a dose, contact your doctor. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands 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 content of a broken tablet or 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 doctor. Call your doctor if you get a skin reaction.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage: Tablet only:** Store the sirolimus blister cards and strips at room temperature, and in the original carton to protect from light. If your sirolimus is dispensed in a bottle, keep in the original container with lid tightly closed. Protect from light.
- **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.
- **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 medication 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 nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- 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 doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help or stop 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 doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor 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 Drug 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 doctor 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 drug interactions with sirolimus. Also, check with your doctor or pharmacist 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 drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.5 F (38 C) or higher
- Chills
- Extreme tiredness, agitation or confusion
- Seizures
- Hallucinations
- Trouble understanding or speaking
- Headache that does not go away
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Feeling dizzy or lightheaded
- Fatigue that interferes with your daily activities
- Wheezing or trouble breathing
- Coughing up yellow, green, or bloody mucus
- Chest pain
- Easy bleeding or bruising
- Pain in your abdomen that does not go away
- 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
- Throwing up more than 3 times a day
- 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
- Pain on one side of your back under your ribs. This is where your kidneys are.
- Pain or burning when you pass urine
- Difficulty urinating
- Feeling like you have to pass urine often, but not much comes out when you do
- Tender or heavy feeling in your lower abdomen
- Cloudy urine and/or urine that smells bad
- Foamy or bubbly-looking urine
- Decreased urine, or very dark urine
- A new rash or a rash that is not relieved by prescribed medicines
- Signs of a local infection such as pain, redness, tenderness, warmth and/or swelling
- 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 you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of child bearing potential should use effective methods of birth control during your cancer treatment and for 12 weeks after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breast feeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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