Sirolimus

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Patient/Caregiver Information

What is Sirolimus?

Sirolimus, also known as rapamycin, is an immunosuppressant medicine. It is used to suppress the body's immune system. It is used to prevent or treat graft-versus host disease in bone marrow transplant patients, and sometimes to treat vascular tumours.

How does it work?

Sirolimus is an immunosuppressant that inhibits cytokine-stimulated T-cell activation and proliferation. Sirolimus binds to a protein within cells to form a complex that blocks the activation of the mammalian Target Of Rapamycin (mTOR), a key regulatory kinase used to activate T-cells.

How is it given?

Sirolimus is available as a tablet or liquid. The liquid strength is 1mg/mL.

Special instructions:

- Sirolimus should be taken at the same time each day, and at the same time in relation to meals. This will help to keep a constant amount of sirolimus in your body.
- Taking the medicine with food may reduce stomach problems.
- Store the oral liquid in the fridge. Once opened, the bottle will expire within 1 month.
- To improve the taste of the oral liquid, the required dose may be diluted in a glass with a quarter cup of water or orange juice. You should drink the medicine right away. Then add a little water or orange juice to the glass, swish it around, and drink that. Never take sirolimus with grapefruit juice.
- If you vomit within 20 minutes after a dose, repeat the full dose again.
- Be sure to drink a lot of liquids while you are taking sirolimus. This lessens the chance of kidney damage.
- Sirolimus can make your skin more sensitive to sunlight. This can cause you to have severe sunburns, skin rashes, redness, and itching. Avoid exposing your skin to sunlight and tanning bulbs. Wear protective clothing, wide-brimmed hats, and sunglasses. Use lip sunblock and sunscreen (SPF15 or higher) on exposed skin.
- To check the level of sirolimus in your body, you will need to have regular blood tests. Your doctor or nurse will inform you when a blood sample is required. On that day, do not take the sirolimus until after your blood test. If you have already taken the sirolimus before the blood test, let your doctor or nurse know.
- Some medicines may either change the blood level of sirolimus or increase the side effects of the drug. These medicines include: cyclosporine, enalapril, erythromycin, fluconazole, itraconazole, metoclopramide, omeprazole, phenytoin, phenobarbital, posaconazole, rifampicin, tacrolimus, and voriconazole. Always give a complete list of medicines you are taking to your doctor or pharmacist. Check with your doctor or pharmacist before starting any new vitamins, herbals, or other medicines.

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Safe Handling:

All chemotherapy taken by mouth can pose a health hazard to caregivers and patients. Take care when handling this medicine and try to prevent the medication from touching your skin. Taking precautions will protect both the patient and the caregiver.

- We suggest that the caregiver wears gloves while handling this medicine. If your skin comes into contact with the medicine, wash your hands or the area of contact right away.
- Prepare a clean area where the drug can be handled safely (away from areas where food is prepared, out of reach of children and away from any fans or air vents). Clean up spills in the area where the medicine is prepared.

If the dose prescribed for your child is too small for you to accurately measure, discuss with your nurse or pharmacist appropriate ways on how to measure the correct dose.

Possible Side Effects:

Listed below, but not limited to, are the more commonly experienced side effects that you may see. The side effects your child might experience may be temporary and some may be permanent.

Likely Happens to 21-100 children out of every 100	**Less Likely** Happens to 5-20 children out of every 100	**Rare but serious** Happens to <5 children out of every 100
▪ Headache ▪ Nausea and vomiting ▪ High blood pressure ▪ Reduced ability of the body to fight infection ▪ Diarrhoea or Constipation ▪ Fever ▪ Tremor (shakiness usually of the hands) ▪ Increases in the levels of certain chemicals in the blood because the kidney is not working as well as normal which may require lowering the dose ▪ Fewer red blood cells in the blood - a low number of red blood cells can make you feel tired and weak ▪ A feeling of weakness and/or tiredness ▪ Pain which may be in the abdomen (belly), back and/or other parts of your body ▪ High levels of sugar in the blood that may require treatment ▪ An increase in the levels of lipids (fats) and cholesterol in your blood which if prolonged could lead to heart problems later in life ▪ Fluid retention and build-up in the tissues usually of the lower legs leading to an increase in weight ▪ Aches and pains in the joints or muscles	▪ Chest pain ▪ Difficulty sleeping or falling asleep ▪ Abnormal levels of magnesium in the body which may require that you take extra magnesium by mouth or vein ▪ Low (*or High*) levels of certain salts in the body like potassium and phosphate which may require treatment ▪ Elevation in the blood of certain enzymes found in the liver which may mean the liver is not working as well ▪ Bladder or kidney infection ▪ Rash or hives that may itch ▪ Acid or upset stomach (heartburn) ▪ Difficulty or discomfort on swallowing ▪ Inflammation of the stomach or esophagus (the tube that leads from the mouth to the stomach) ▪ Too much gas produced in the intestines ▪ Loss of appetite ▪ Shortness of breath and/or a tight feeling in the chest with wheezing and shortness of breath (asthma) ▪ Increased cough ▪ Throat or chest infection ▪ Flu type symptoms with fever, tiredness, aches and pains ▪ Changes in your brain function such that you have difficulty in thinking clearly, are sleepy, depressed, dizzy, anxious, are nervous, have changes in your mood, numbness and tingling in the fingers and toes ▪ Fewer white blood cells and platelets in the blood - a low number of white blood cells can make it easier to get infections and a low number of platelets causes you to bruise and bleed more easily ▪ Skin sores	▪ Fluid build-up in the lungs that can make you feel short of breath ▪ A fast heartbeat which may cause pain in the chest ▪ An allergic reaction ▪ Abnormal clotting of the small blood vessels of the kidney which could lead to kidney failure or to damage to other organs of the body ▪ Inflammation and clotting of blood vessels which can lead to pain and swelling in the area of the clot ▪ Bleeding which can occur in the head, stools, the nose, urine and other parts of the body ▪ Damage to the heart muscle which may make you tired, weak, feel short of breath, and retain fluid ▪ Infections including those caused by bacteria, virus, and fungus which could be located in the skin, blood, throat, sinuses, lungs or abdomen (belly) ▪ Fluid collection in the abdomen (belly) which makes it look larger ▪ Kidney damage (which may be permanent) ▪ Diabetes mellitus may develop later on - a condition where the sugar in the blood is not appropriately controlled and may require treatment with insulin by injection or drugs taken by mouth ▪ Damage to the heart muscle which may make you tired, weak, feel short of breath, and retain fluid and may require treatment ▪ A stoppage (or blockage) of the intestine which may require treatment

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▪ Pimples	▪ Wounds may be slower to heal Excessive hair growth such as on the face, eyebrows, arms and legs ▪ Bleeding or tender gums, overgrowth of gum tissue ▪ Changes in your vision or a decrease in vision ▪ Damage to the eye which makes the vision blurred or less clear (cataract) ▪ Ear pain or ringing in the ears ▪ High levels of uric acid in the blood which could damage the kidneys	▪ Thinning of the bone (osteoporosis)which could lead to weakness of the bone, bone fractures or delay in healing of fractures ▪ Damage to the bone which could lead to arthritis pain ▪ Excessive growth of white blood cells that may lead to lymphoma a cancer of the white blood cells ▪ Increased chance of skin cancers

This information sheet is a brief overview. Each individual can respond differently to the medication, it is vital that you communicate all signs and symptoms you observe to your doctor or nurse.

If you have any questions about the information provided please discuss them with your oncologist or haematologist.

Further information can be obtained from your doctor, nurse or pharmacist or at the following website: http://medsafe.govt.nz/consumers/medicine/where.asp