

MEDICATION GUIDE

Sirolimus (sir OH li mus) Tablets

What is the most important information I should know about sirolimus tablets?

Sirolimus tablets can cause serious side effects, including:

1. Increased risk of getting infections. Serious infections can happen including infections caused by viruses, bacteria, and fungi (yeast). Your doctor may put you on medicine to help prevent some of these infections.

Call your doctor right away if you have symptoms of infection including fever or chills while taking sirolimus tablets.

2. Increased risk of getting certain cancers. People who take sirolimus tablets have a higher risk of getting lymphoma, and other cancers, especially skin cancer. Talk with your doctor about your risk for cancer.

Sirolimus 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 sirolimus after a liver or lung transplant. You should not take sirolimus tablets if you have had a liver or lung transplant without talking with your doctor.

See the section “What are the possible side effects of sirolimus tablets?” for information about other side effects of sirolimus tablets.

What is sirolimus tablets?

Sirolimus tablets are a prescription medicine used to prevent rejection (anti-rejection medicine) in people 13 years of age and older 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.

Sirolimus tablets are used with other medicines called cyclosporine (Gengraf, Neoral, Sandimmune), and corticosteroids. Your doctor will decide:

- if sirolimus tablets are right for you, and
- how to best use it with cyclosporine and corticosteroids after your transplant.

It is not known if sirolimus tablets are safe and effective in children under 13 years of age.

Who should not take sirolimus tablets?

Do not take sirolimus tablets if you are allergic to sirolimus or any of the other ingredients in sirolimus tablets. See the end of this leaflet for a complete list of ingredients in sirolimus tablets.

What should I tell my doctor before taking sirolimus tablets?

- have liver problems
- have skin cancer or it runs in your family
- have high cholesterol or triglycerides (fat in your blood)
- are pregnant or are a female who can become pregnant. Sirolimus can harm your unborn baby. You should not become pregnant during treatment with sirolimus tablets and for 12 weeks after ending treatment with sirolimus tablets. In order to avoid pregnancy, a female who can get pregnant should use effective birth control during treatment and for 12 weeks after your final dose of sirolimus tablets. Talk with your doctor about what birth control method is right for you during this time. Tell your doctor right away if you become pregnant or think you are pregnant during treatment with sirolimus tablets or within 12 weeks after your final dose of sirolimus tablets.
- It is not known whether sirolimus passes into breast milk; however, there is a risk of serious side effects in breastfed infants. You and your doctor should decide about the best way to feed your baby if you take sirolimus tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Using sirolimus tablets with certain medicines may affect each other causing serious side effects. Sirolimus may affect the way other medicines work, and other medicines may affect how sirolimus works.

Especially tell your doctor if you take:

- a medicine to lower your cholesterol or triglycerides
- cyclosporine (including Gengraf, Neoral, Sandimmune) or tacrolimus (Prograf) or other medicines that suppress the immune system
- an antibiotic
- an antifungal medicine
- a medicine for high blood pressure or heart problems
- an anti-seizure medicine
- medicines used to treat stomach acid, ulcers, or other gastrointestinal problems
- bromocriptine mesylate (Parlodel, Cycloset)
- danazol
- medicines to treat HIV or hepatitis C
- St. John’s Wort

How should I take sirolimus tablets?

- Take sirolimus tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how much sirolimus tablets to take and when to take it. Do not change your dose of sirolimus tablets unless your doctor tells you to.
- If you also take cyclosporine (Gengraf, Neoral, Sandimmune), you should take your sirolimus tablets and cyclosporine about 4 hours apart.
- Do not stop taking sirolimus tablets or your other anti-rejection medicines unless your doctor tells you to.
- Your doctor will check the levels of sirolimus in your blood. Your doctor may change your dose of sirolimus tablets depending on your blood test results.
- Sirolimus tablets are taken by mouth 1 time each day.
- Do not crush, chew, or split sirolimus tablets. Tell your doctor if you cannot swallow sirolimus tablets. Your doctor can prescribe sirolimus as a solution.
- Take each dose of sirolimus tablets the same way, either with or without food. Food can affect the amount of medicine that gets into your bloodstream. Taking each dose of sirolimus tablets the same way helps keep your blood levels of sirolimus tablets more stable. Do not take sirolimus tablets with grapefruit juice.
- If you have taken more medicine than you were told, contact a doctor or go to the nearest hospital emergency department right away.

What should I avoid while taking sirolimus tablets?

- Avoid receiving live vaccines while taking sirolimus tablets. Some vaccines may not work as well while you are taking sirolimus tablets.
- Limit your time in sunlight and UV light. Cover your skin with clothing and use a broad spectrum sunscreen with a high protection factor because of the increased risk for skin cancer with sirolimus tablets.

What are the possible side effects of sirolimus tablets?

Sirolimus tablets may cause serious side effects, including:

- See “**What is the most important information I should know about sirolimus tablets?**”
- **Serious allergic reactions.** Tell your doctor or get medical help right away if you get any of following symptoms of an allergic reaction:
 - swelling of your face, eyes, or mouth
 - chest pain or tightness
 - trouble breathing or wheezing
 - feeling dizzy or faint
 - throat tightness
 - rash or peeling of your skin
- **Swelling (edema).** Fluid may collect in your hands and feet and in various tissues of your body, including in the sac around your heart or lungs. Call your doctor if you have trouble breathing.
- **Poor wound healing.** Sirolimus may cause your wounds to heal slowly or not heal well. Tell your doctor if you have any redness or drainage, your wound does not heal, or the wound opens up.
- **Increased levels of cholesterol and triglycerides (lipids or fat) in your blood.** Your doctor should do blood tests to check

your lipids during treatment with sirolimus. Your doctor may prescribe treatment with diet, exercise, or medicine if your lipid levels are too high. During treatment with sirolimus tablets, your blood levels of cholesterol and triglycerides may remain high even if you follow your prescribed treatment plan.

- **Effects on kidney function.** When sirolimus tablets are taken with cyclosporine (Gengraf, Neoral, Sandimmune), the function of your transplanted kidney may be affected. Your doctor should regularly do tests to check your kidney function while you are taking sirolimus tablets with cyclosporine (Gengraf, Neoral, Sandimmune).
- **Increased protein in your urine.** Your doctor may regularly test your urine protein.
- **Increased risk for viral infections.**
- Certain viruses can live in your body and cause active infections when your immune system is weak. BK virus can affect how your kidney works and cause your transplanted kidney to fail.
- A certain virus can cause a rare serious brain infection called Progressive Multifocal Leukoencephalopathy (PML). PML usually causes death or severe disability. Call your doctor right away if you notice any new or worsening medical problems such as:
 - confusion
 - sudden change in thinking, walking, strength on one side of your body
 - other problems that have lasted over several days
- **Lung or breathing problems.** This can sometimes lead to death. Tell your doctor if you have a new or worsening cough, shortness of breath, difficulty breathing or any new breathing problems. Your doctor may need to stop sirolimus tablets or lower your dose.
- **Blood clotting problems.** When sirolimus tablets are taken with cyclosporine or tacrolimus, you may develop a blood clotting problem. Tell your doctor if you get any unexplained bleeding or bruising.
- **Possible harm to your unborn baby.** Sirolimus can harm your unborn baby. You should not become pregnant during treatment with sirolimus tablets and for 12 weeks after ending treatment with sirolimus tablets. See “**What should I tell my doctor before taking sirolimus tablets?**”.

The most common side effects of sirolimus tablets in people with renal transplant include:

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|-------------------------------------------|------------------------------------------------------|
| ○ high blood pressure | ○ urinary tract infection |
| ○ pain (including stomach and joint pain) | ○ low red blood cell count (anemia) |
| ○ diarrhea | ○ nausea |
| ○ headache | ○ low platelet count (cells that help blood to clot) |
| ○ fever | ○ high blood sugar (diabetes) |

Other side effects that may occur with sirolimus tablets:

- Sirolimus tablets may affect fertility in females and may affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.
- Sirolimus tablets may affect fertility in males and may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.

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

These are not all of the possible side effects of sirolimus tablets. For more information ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sirolimus tablets?

Sirolimus tablets:

- Store sirolimus tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Bottles: Keep the bottle of sirolimus tablets tightly closed.

Do not use sirolimus tablets after the expiration date. The expiration date refers to the last day of that month.

Safely throw away medicine that is out of date or no longer needed.

Keep sirolimus tablets and all medicines out of the reach of children.

General Information about the safe and effective use of sirolimus tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sirolimus tablets for a condition for which it was not prescribed. Do not give sirolimus tablets to other people even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about sirolimus tablets. If you would like more information talk to your doctor. You can ask your pharmacist or doctor for information about sirolimus that is written for health professionals.

For more information, call Glenmark Pharmaceuticals Inc., USA at 1 (888) 721-7115.

What are the ingredients in sirolimus tablets?

Active ingredients: sirolimus

Inactive ingredients: croscarmellose sodium, *d*-alpha tocopherol, edetate disodium, glyceryl behenate, hypromellose, lactose monohydrate, microcrystalline cellulose, poloxamer 188, polyethylene glycol, sucrose and titanium dioxide. Additionally, the 0.5 mg dosage strength also contains: iron oxide black, iron oxide yellow and iron oxide red and the 2 mg dosage strength also contains: D&C yellow #10, FD&C yellow #6 and FD&C blue #2.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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