

## MEDICATION GUIDE

### Sirolimus (sir oh' li mus) Tablets

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

Sirolimus 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.

2. **Increased risk of getting certain cancers.** People who take Sirolimus 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 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?” for information about other side effects of sirolimus.**

#### What is sirolimus?

Sirolimus is 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 is used with other medicines called cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>), and corticosteroids. Your doctor will decide:

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

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

Sirolimus is a prescription medicine also used to treat lymphangioleiomyomatosis (LAM). LAM is a rare progressive lung disease that affects predominantly women of childbearing age.

#### Who should not take sirolimus?

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

#### What should I tell my doctor before taking sirolimus?

- 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 and for 12 weeks after ending treatment with sirolimus. 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. 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 or within 12 weeks after your final dose of sirolimus.
- 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.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements. Using sirolimus 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<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>) or tacrolimus (Prograf<sup>®</sup>) 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<sup>®</sup>, Cycloset<sup>®</sup>)
- danazol
- medicines to treat HIV or hepatitis C
- St. John's Wort

#### How should I take sirolimus?

- Take sirolimus exactly as your doctor tells you to take it.
- Your doctor will tell you how much sirolimus to take and when to take it. Do not change your dose of sirolimus unless your doctor tells you to.
- If you also take cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>), you should take your sirolimus and cyclosporine about 4 hours apart.
- Do not stop taking sirolimus 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 depending on your blood test results.
- Sirolimus is 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 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 the same way helps keep your blood levels of sirolimus more stable. Do not take sirolimus 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?

- Avoid receiving live vaccines while taking sirolimus. Some vaccines may not work as well while you are taking sirolimus.
- 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.

#### What are the possible side effects of sirolimus?

**Sirolimus may cause serious side effects, including:**

- See “**What is the most important information I should know about sirolimus?**”
- **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
  - trouble breathing or wheezing
  - throat tightness
  - chest pain or tightness
  - feeling dizzy or faint
  - 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, your blood levels of cholesterol and triglycerides may remain high even if you follow your prescribed treatment plan.
- **Effects on kidney function.** When sirolimus is taken with cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>), 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 with cyclosporine (Gengraf<sup>®</sup>, Neoral<sup>®</sup>, Sandimmune<sup>®</sup>).
- **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 or lower your dose.
- **Blood clotting problems.** When sirolimus is 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 and for 12 weeks after ending treatment with sirolimus. See “What should I tell my doctor before taking sirolimus?”.

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

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

**Other side effects that may occur with sirolimus:**

- Sirolimus 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 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.

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. For more information ask your doctor or pharmacist.

**Please address medical inquiries to [MedicalAffairs@zydususa.com](mailto:MedicalAffairs@zydususa.com) or Tel.: 1-877-993-8779.**

**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?**

- Store at 20° to 25°C (68° to 77°F).
- Blister cards and strips: Keep the tablets in the original blister container and use the outer carton to protect blister cards and strips from light.
- Bottles: Keep the bottle of sirolimus tablets tightly closed.

Do not use sirolimus 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 and all medicines out of the reach of children.

**General Information about the safe and effective use of sirolimus**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sirolimus for a condition for which it was not prescribed. Do not give sirolimus 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. 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.

**What are the ingredients in sirolimus tablets?**

Active ingredients: sirolimus.

Inactive ingredients: citric acid monohydrate, crospovidone, FD&C yellow #5 Aluminum Lake, glyceryl monooleate, hypromellose, iron oxide yellow, lactose monohydrate, microcrystalline cellulose, poloxamer, polyethylene glycol, povidone, sucrose, talc, titanium dioxide and vitamin E acetate.

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