

Sirolimus Side Effects

In Summary

Commonly reported side effects of sirolimus include: upper respiratory tract infection and urinary tract infection. See below for a comprehensive list of adverse effects.

For the Consumer

Applies to **sirolimus**: oral solution, oral tablet

Warning

Oral route (Solution; Tablet)

Increased susceptibility to infection and the possible development of lymphoma and other malignancies may result from **immunosuppression**. Only physicians experienced in immunosuppressive therapy and management of renal transplant patients should prescribe sirolimus for prophylaxis of organ rejection in patients receiving renal transplants, and they should have complete information requisite for the followup of the patient. The use of sirolimus in combination with **cyclosporine** or **tacrolimus** was associated with excess mortality, graft loss, and hepatic artery thrombosis in studies in de novo **liver transplant** patients. Cases of bronchial anastomotic dehiscence, most fatal, have been reported in de novo lung transplant patients when sirolimus was used as part of an immunosuppressive regimen. The safety and efficacy of sirolimus as immunosuppressive therapy have not been established in liver or lung transplant patients, and such use is not recommended.

Side effects requiring immediate medical attention

Along with its needed effects, sirolimus may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking sirolimus:

More common

- Abdominal or stomach cramps or pain
- accumulation of pus

- anxiousness, unexplained
- **backache**
- black or red, tarry stools
- bleeding from the gums or nose
- blurred vision
- body aches or pain
- bone pain
- bruising
- burning or stinging of the skin
- burning while urinating
- burning, dry, or itching eyes
- burning, tingling, **numbness**, or pain in the hands, arms, feet, or legs
- change in mental status
- changes in skin color
- chest pain
- chills
- confusion
- convulsions (**seizures**)
- cough
- dark or bloody urine
- deafness
- decreased urine output
- decreased vision
- difficulty with breathing or swallowing
- dilated neck veins
- discharge from the eyes
- **dizziness**
- drowsiness

- dry mouth
- earache
- excessive tearing
- extreme fatigue
- **eye pain**
- facial hair growth in females
- faintness or lightheadedness when getting up from lying or sitting position
- fast, slow, or **irregular heartbeat**
- fever
- flushing or redness of the skin, especially on the face and neck
- general feeling of discomfort or illness
- increased hunger
- increased menstrual flow or **vaginal bleeding**
- itching, pain, redness, swelling, tenderness, or warmth on the skin
- lack or loss of appetite
- large, flat, blue, or purplish patches in the skin
- loss of sexual ability, desire, drive, or performance
- loss of voice
- muscle pain
- **nasal congestion**
- **nausea** or **vomiting**
- numbness or tingling around the lips, hands, or feet
- pain in the chest, groin, or legs, especially the calves
- painful **cold sores** or blisters on the lips, nose, eyes, or genitals
- pale skin
- prolonged bleeding from cuts
- rapid heartbeat
- rash

- red or dark brown urine
- redness or swelling in the ear
- redness, pain, or swelling of the eye, eyelid, or inner lining of the eyelid
- ringing in the ears
- **runny nose**
- sensation of pins and needles
- **severe constipation**
- severe vomiting
- severe, sudden **headache**
- slurred speech
- **sore throat**
- sores or white spots on the lips or in the mouth
- stomach pain or upset
- sudden decrease in the amount of urine
- sudden loss of coordination
- sudden, severe weakness or numbness in the arm or leg
- sudden, unexplained shortness of breath
- sweating
- swollen, painful, or tender lymph glands in the neck, armpit, or groin
- tenderness, pain, swelling, warmth, skin discoloration, and prominent superficial veins over affected area
- tremor
- ulcers on the lips or in the mouth
- unusual tiredness or weakness
- vision changes
- weakness or heaviness of the legs
- white patches in the mouth or on the tongue
- yellow skin and eyes

Less common

- **Bloating**
- change in size, shape, or color of existing mole
- hoarseness
- mole that leaks fluid or bleeds
- new mole
- pains in the stomach, side or abdomen, possibly radiating to the back
- skin ulcer or sores

Incidence not known

- Abnormal wound healing
- headache
- **hives** or itching
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- nails loose or detached
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- swelling of the arms or legs
- yellow nails lacking a cuticle

Side effects not requiring immediate medical attention

Some side effects of sirolimus may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

More common

- Abnormal vision
- **acne**
- **belching**
- blistering, crusting, irritation, itching, or reddening of the skin

- burning feeling in the chest or stomach
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feeling
- constipation
- continuing ringing or buzzing or other unexplained noise in the ears
- cracked, dry, or scaly skin
- crying
- decrease in frequency of urination
- degenerative disease of the joint
- depersonalization
- **diarrhea**
- difficulty with moving
- difficulty with passing urine (dribbling)
- dysphoria
- ear pain
- enlarged abdomen or stomach
- euphoria
- excess air or gas in the stomach or intestines
- excessive muscle tone, muscle tension or tightness
- fear
- feeling sad or empty
- **hearing loss**
- **heartburn**
- inability to have or keep an erection
- increase in heart rate
- increased hair growth, especially on the face
- increased urge to urinate during the night
- **indigestion**
- irritation in the mouth

- joint pain or swelling
- leg cramps
- loss of bladder control
- loss of energy or weakness
- loss of interest or pleasure
- loss of strength
- lower abdominal or stomach pain
- muscle aches, pain, stiffness, or weakness
- nervousness
- pain in the back, ribs, arms, or legs
- pain or burning in the throat
- pain or tenderness around the eyes and cheekbones
- paranoia
- **pelvic pain**
- quick to react or overreact emotionally
- rapid breathing
- rapidly changing moods
- inflammation, redness, or swelling of the gums or mouth
- shaking or trembling
- shivering
- sleepiness
- sunken eyes
- swelling
- swelling of the scrotum
- tender or enlarged gums
- tenderness in the stomach area
- thickening of the skin
- trouble concentrating

- trouble sleeping
- waking to urinate at night

For Healthcare Professionals

Applies to sirolimus: oral solution, oral tablet

Respiratory

Very common (10% or more): **Dyspnea** (up to 30%), upper respiratory infection (up to 26%), **pharyngitis** (up to 21%)

Common (1% to 10%): **Pneumonia**, epistaxis, **pleural effusion**, epistaxis

Uncommon (0.1% to 1%): Pulmonary hemorrhage

Rare (less than 0.1%): Alveolar proteinosis

Frequency not reported: Pleural effusion, alveolar proteinosis^[Ref]

Metabolic

Very common (10% or more): Hypertriglyceridemia (up to 58%), hypercholesterolemia (up to 46%), **hypokalemia**, hypophosphatemia, hyperglycemia

Common (1% to 10%): Abnormal healing, increased lactic dehydrogenase (LDH), hypokalemia, **diabetes mellitus**^[Ref]

Cardiovascular

Very common (10% or more): Peripheral **edema** (up to 58%), hypertension (up to 49%), chest pain (up to 24%), edema (up to 18%), lymphocele

Common (1% to 10%): Venous **thromboembolism** (including **pulmonary embolism**, **deep venous thrombosis**), **tachycardia**

Uncommon (0.1% to 1%): Pericardial effusion (including hemodynamically significant effusions in children and adults), lymphedema

Rare (less than 0.1%): Pericardial effusion^[Ref]

Gastrointestinal

Very common (10% or more): Constipation (up to 38%), **abdominal pain** (up to 36%), diarrhea (up to 35%), nausea (up to 31%), vomiting (up to 25%), **dyspepsia** (up to 25%)

Common (1% to 10%): **Stomatitis**^[Ref]

General

The most common adverse reactions associated with this drug are peripheral edema, hypertriglyceridemia, hypertension, hypercholesterolemia, creatinine increased, constipation, abdominal pain, diarrhea, headache, fever, urinary tract infection, anemia, nausea, arthralgia, pain, and **thrombocytopenia**.^[Ref]

Hematologic

Very common (10% or more): Anemia (up to 33%), thrombocytopenia (up to 30%), blood lactate dehydrogenase increased, blood creatinine increased

Common (1% to 10%): Thrombocytopenic purpura/hemolytic uremic syndrome, leukopenia, **neutropenia**, aspartate aminotransferase increased, alanine aminotransferase increased

Uncommon (0.1% to 1%): **Pancytopenia**

Frequency not reported: Capillary leak syndrome^[Ref]

Genitourinary

Very common (10% or more): Urinary tract infection (up to 33%)

Common (1% to 10%): Pyelonephritis, decline in renal function (creatinine increased) in long-term combination of **cyclosporine** with this drug, **ovarian cysts**, **menstrual disorders** (including **amenorrhea** and **menorrhagia**), proteinuria

Postmarketing reports: Azoospermia^[Ref]

Musculoskeletal

Very common (10% or more): Arthralgia (up to 31%)

Common (1% to 10%): Bone necrosis^[Ref]

Nervous system

Very common (10% or more): Headache (up to 34%)

Common (1% to 10%): **Osteonecrosis**, tremor, **insomnia**^[Ref]

Dermatologic

Very common (10% or more): Acne (up to 22%), rash (up to 20%)

Common (1% to 10%): **Herpes zoster**, herpes simplex

Uncommon (0.1% to 1%): Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), leukopenia, melanoma, squamous cell carcinoma, **basal cell carcinoma**^[Ref]

Renal

Very common (10% or more): Creatinine increased (up to 40%)

Uncommon (0.1% to 1%): **Nephrotic syndrome**

Frequency not reported: Focal segmental glomerulo-sclerosis, BK virus associated nephropathy, nephrotic syndrome, higher serum creatinine levels, lower glomerular filtration rates^[Ref]

Ocular

Frequency not reported: Eyelid edema^[Ref]

Hepatic

Common (1% to 10%): **Liver function tests** abnormal

Frequency not reported: Hepatic failure, hepatic artery thrombosis^[Ref]

Hypersensitivity

Rare (less than 0.1%): Hypersensitivity reactions, including anaphylactic/ anaphylactoid reactions, **angioedema**, exfoliative dermatitis, and hypersensitivity **vasculitis**^[Ref]

Other

Very common (10% or more): Fever (up to 34%), pain (up to 29%)

Common (1% to 10%): Impaired healing^[Ref]

Oncologic

Common (1% to 10%): Skin **cancer, lymphoma**/post-transplant lymphoproliferative disorder

Frequency not reported: Hepatocellular adenoma and carcinoma, testicular adenoma^[Ref]

Immunologic

Common (1% to 10%): **Sepsis**, pneumonia, pyelonephritis, herpes simplex, fungal, viral, and bacterial infections (such as mycobacterial infections, including **tuberculosis, Epstein-Barr virus**, CMV, and Herpes zoster), mycobacterial infections (including M tuberculosis), cytomegalovirus (CMV), Epstein-Barr virus

Frequency not reported: Clostridium difficile enterocolitis^[Ref]

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Some side effects may not be reported. You may report them to the **FDA**.