

**Patient Information**  
**Tacrolimus Capsules, USP**  
(ta-KROE-li-mus)

Read this Patient Information before you start taking tacrolimus capsules and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is the most important information I should know about Tacrolimus Capsules USP?**

**Tacrolimus Capsules USP can cause serious side effects, including:**

- **Increased risk of cancer.** People who take Tacrolimus Capsules USP have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).
- **Increased risk of infection.** Tacrolimus Capsules USP is a medicine that affects your immune system. Tacrolimus Capsules USP can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving Tacrolimus Capsules USP that can cause death. **Call your healthcare provider right away if you have any symptoms of an infection, including:**
  - o fever
  - o muscle aches
  - o sweats or chills
  - o warm, red, or painful
  - o cough or flu-like symptoms
  - o areas on your skin

**What is Tacrolimus Capsules USP?**

- Tacrolimus Capsules USP is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney, liver, heart or lung transplant.
- Tacrolimus Capsules USP are types of tacrolimus immediate-release drugs and they are not the same as tacrolimus extended-release tablets or tacrolimus extended-release capsules. Your healthcare provider should decide what medicine is right for you.

**Who should not take Tacrolimus Capsules USP?**

**Do not take Tacrolimus Capsules USP if you:**

- are allergic to tacrolimus or any of the ingredients in Tacrolimus Capsules USP. See the end of this leaflet for a complete list of ingredients in Tacrolimus Capsules USP.

**What should I tell my healthcare provider before taking Tacrolimus Capsules USP?**

**Before taking Tacrolimus Capsules USP, tell your healthcare provider about all of your medical conditions, including if you:**

- plan to receive any live vaccines. People taking Tacrolimus Capsules USP should not receive live vaccines.
- have or have had liver, kidney, or heart problems.
- are pregnant or plan to become pregnant. Tacrolimus Capsules USP can harm your unborn baby.
  - o If you are able to become pregnant, you should use effective birth control before and during treatment with Tacrolimus Capsules USP. Talk to your healthcare provider before starting treatment with Tacrolimus Capsules USP about birth control methods that may be right for you.
  - o Males who have female partners who are able to become pregnant should also use effective birth control before and during treatment with Tacrolimus Capsules USP. Talk to your healthcare provider before starting treatment with Tacrolimus Capsules USP about birth control methods that may be right for you.
  - o There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with Tacrolimus Capsules USP. The purpose of this registry is to collect information about the health of you and your baby. To enroll in this voluntary registry, call 1-877-955-6877 or go to <https://www.transplantpregnancyregistry.org/>.
- are breastfeeding or plan to breastfeed. Tacrolimus Capsules USP passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking Tacrolimus Capsules USP.

**Tell your healthcare provider about all the medicines you take, and when you start a new medicine or stop taking a medicine, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements.**

**Especially tell your healthcare provider if you take:**

- sirolimus (RAPAMUNE): You should not take Tacrolimus Capsules USP if you take sirolimus

- cyclosporine (GENGRAF, NEORAL, and SANDIMMUNE)
- medicines called aminoglycosides that are used to treat bacterial infections
- ganciclovir (CYTOVENE IV, VALCYTE)
- amphotericin B (ABELCET, AMBISOME)
- cisplatin
- antiviral medicines called nucleoside reverse transcriptase inhibitors
- antiviral medicines called protease inhibitors
- water pill (diuretic)
- medicine to treat high blood pressure
- nelfinavir (VIRACEPT)
- telaprevir (INCIVEK)
- boceprevir
- ritonavir (KALETRA, NORVIR, TECHNIVIE, VIEKIRA PAK, VIEKIRA XR)
- letemovir (PREVYMIS)
- ketoconazole
- itraconazole (ONMEL, SPORANOX)
- voriconazole (VFEND)
- caspofungin (CANCIDAS)
- clarithromycin (BIAXIN, BIAXIN XL, PREVPAC)
- rifampin (RIFADIN, RIFAMATE, RIFATER, RIMACTANE)
- rifabutin (MYCOBUTIN)
- amiodarone (NEXTERONE, PACERONE)
- cannabidiol (EPIDIOLEX)

Ask your healthcare provider or pharmacist if you are not sure if you take any of the medicines listed above. Tacrolimus Capsules USP may affect the way other medicines work, and other medicines may affect how Tacrolimus Capsules USP works.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

**How should I take Tacrolimus Capsules USP?**

- Take Tacrolimus Capsules USP exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Tacrolimus Capsules USP to take and when to take it.
- Your healthcare provider may change your Tacrolimus Capsules USP dose if needed. **Do not** stop taking or change your dose of Tacrolimus Capsules USP without talking to your healthcare provider.
- Take Tacrolimus Capsules USP with or without food.
- Take Tacrolimus Capsules USP the same way every day. For example, if you choose to take Tacrolimus Capsules USP with food, you should always take Tacrolimus Capsules USP with food.
- Take Tacrolimus Capsules USP at the same time each day, 12 hours apart. For example, if you take your first dose at 7:00 a.m., you should take your second dose at 7:00 p.m.
- Taking Tacrolimus Capsules USP at the same time each day helps to keep the amount of medicine in your body at a steady level.
- If you take too much Tacrolimus Capsules USP, call your healthcare provider or go to the nearest hospital emergency room right away.

**Tacrolimus capsules USP:**

- **Do not** open or crush Tacrolimus Capsules USP.

**What should I avoid while taking Tacrolimus Capsules USP?**

- While you take Tacrolimus Capsules USP you should not receive any live vaccines.
- Limit the amount of time you spend in sunlight and avoid exposure to ultraviolet (UV) light, such as tanning machines. Wear protective clothing and use a sunscreen with a high sun protection factor (SPF).
- **Do not** eat grapefruit or drink grapefruit juice during treatment with Tacrolimus Capsules USP.

**What are the possible side effects of Tacrolimus Capsules USP?**

**Tacrolimus Capsules USP may cause serious side effects, including:**

- See “What is the most important information I should know about Tacrolimus Capsules USP?”
- **problems from medicine errors.** People who take Tacrolimus Capsules USP have sometimes been given the wrong type of tacrolimus product. **Tacrolimus extended-release medicines are not the same as Tacrolimus Capsules USP** and cannot be substituted for each other. **Check your**

**Tacrolimus Capsules USP when you get a new prescription and before you take it to make sure you have received Tacrolimus Capsules USP.**

- Check with the pharmacist and call your healthcare provider if you think you were given the wrong medicine.
- **high blood sugar (diabetes).** Your healthcare provider may do blood tests to check for diabetes while you take Tacrolimus Capsules USP. Call your healthcare provider right away if you have any symptoms of high blood sugar, including:
  - frequent urination
  - drowsiness
  - increased thirst or hunger
  - loss of appetite
  - blurred vision
  - fruity smell on your breath
  - confusion
  - nausea, vomiting, or stomach pain
- **kidney problems.** Kidney problems are a serious and common side effect of Tacrolimus Capsules USP. Your healthcare provider may do blood tests to check your kidney function while you take Tacrolimus Capsules USP.
- **nervous system problems.** Nervous system problems are a serious and common side effect of Tacrolimus Capsules USP. Call your healthcare provider right away if you get any of these symptoms while taking Tacrolimus Capsules USP. These could be signs of a serious nervous system problem:
  - headache
  - changes in behavior
  - confusion
  - coma
  - seizures
  - tremors
  - changes in your vision
  - numbness and tingling
- **high levels of potassium in your blood.** Your healthcare provider may do blood tests to check your potassium level while you take Tacrolimus Capsules USP.
- **high blood pressure.** High blood pressure is a serious and common side effect of Tacrolimus Capsules USP. Your healthcare provider will monitor your blood pressure while you take Tacrolimus Capsules USP and may prescribe blood pressure medicine for you, if needed. Your healthcare provider may instruct you to check your blood pressure at home.
- **changes in the electrical activity of your heart (QT prolongation).**
- **heart problems (myocardial hypertrophy).** Tell your healthcare provider right away if you get any of these symptoms of heart problems while taking Tacrolimus Capsules USP:
  - shortness of breath
  - feel lightheaded
  - chest pain
  - feel faint
- **severe low red blood cell count (anemia).**
- **blood clotting problems:** Tell your healthcare provider right away if you have fever and bruising under the skin that may appear as red dots, with or without unexplained tiredness, confusion, yellowing of the skin or eyes, decreased urination. When taken with sirolimus or everolimus, the risk of developing these symptoms may increase.

**The most common side effects of Tacrolimus Capsules USP in people who have received a kidney, liver, heart or lung transplant are:**

- infections in general, including cytomegalovirus (CMV) infection
- swelling of the hands, legs, ankles, or feet
- weakness
- tremors (shaking of the body)
- pain
- constipation
- high levels of fat in your blood
- diarrhea
- high levels of potassium in your blood
- headache
- low red blood cell count (anemia)
- stomach pain
- low white blood cell count
- trouble sleeping
- fever
- nausea
- numbness or tingling in your hands and feet
- high blood sugar (diabetes)
- inflammation of your airway (bronchitis)
- low levels of magnesium in your blood
- fluid around your heart
- low levels of phosphate in your blood

Tell your healthcare provider if you have any side effect that bothers

you or that does not go away. These are not all the possible side effects of Tacrolimus Capsules USP. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store Tacrolimus Capsules USP?**

Store Tacrolimus Capsules USP at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep Tacrolimus Capsules USP and all medicines out of the reach of children.**

**General information about the safe and effective use of Tacrolimus Capsules USP.**

- Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Tacrolimus Capsules USP for a condition for which it was not prescribed. Do not give Tacrolimus Capsules USP to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Tacrolimus Capsules USP that is written for health professionals.
- This Patient Information leaflet summarizes the most important information about Tacrolimus Capsules USP. If you would like more information, talk to your healthcare provider

**What are the ingredients in Tacrolimus Capsules USP?**

**Active ingredient:** Tacrolimus USP

**Inactive ingredients:**

Tacrolimus Capsules USP: croscarmellose sodium, hypromellose, lactose anhydrous, and magnesium stearate. The 0.5 mg capsule shell contains ferric oxide, gelatin, and titanium dioxide. The 1 mg capsule shell contains gelatin and titanium dioxide. The 5 mg capsule shell contains ferric oxide, gelatin, and titanium dioxide.

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For more information, call Jubilant Cadista Pharmaceuticals Inc. at 800-313-4623 or [www.cadista.com](http://www.cadista.com) or FDA at 1-800-FDA-1088. This Patient Information has been approved by the U.S. Food and Drug Administration.

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