

Tacrolimus Capsules, USP, for oral use **(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?

Tacrolimus capsules can cause serious side effects, including:

- **Increased risk of cancer.** People who take tacrolimus capsules have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).
- **Increased risk of infection.** Tacrolimus capsules are a medicine that affect your immune system. Tacrolimus capsules can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving tacrolimus capsules 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 areas on your skin |
| o cough or flu-like symptoms | |

What are tacrolimus capsules?

- Tacrolimus capsules are a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney, liver, or heart transplant.
- Tacrolimus capsules are a type of tacrolimus immediate-release drug 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?

Do not take tacrolimus capsules if you:

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

What should I tell my healthcare provider before taking tacrolimus capsules?

Before taking tacrolimus capsules, tell your healthcare provider about all of your medical conditions, including if you:

- plan to receive any vaccines. People taking tacrolimus capsules should not receive live vaccines.
- have or have had liver, kidney, or heart problems.
- are pregnant or plan to become pregnant. Tacrolimus capsules 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. Talk to your healthcare provider before starting treatment with tacrolimus capsules 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. Talk to your healthcare provider before starting treatment with tacrolimus capsules 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. 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 passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking tacrolimus capsules.
 - plan to have children. Tacrolimus capsules may affect the ability to have children in females and males (fertility problems).

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 if you take sirolimus.
- cyclosporine (GENGRAF®, NEORAL®, and SANDIMUNE®)
- 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™)
- letermovir (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 may affect the way other medicines work, and other medicines may affect how tacrolimus capsules work.

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?

- Take tacrolimus capsules exactly as your healthcare provider tells you to take them.
- Your healthcare provider will tell you how many tacrolimus capsules to take and when to take them.
Your healthcare provider may change your tacrolimus capsules dose if needed. **Do not** stop taking or change your dose of tacrolimus capsules without talking to your healthcare provider.
- Take tacrolimus capsules with or without food.
- Take tacrolimus capsules the same way every day. For example, if you choose to take tacrolimus capsules with food, you should always take tacrolimus capsules with food.
- Take tacrolimus capsules 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 at the same time each day helps to keep the amount of medicine in your body at a steady level.
- If you take too many tacrolimus capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

Tacrolimus capsules:

- **Do not** open or crush tacrolimus capsules.

What should I avoid while taking tacrolimus capsules?

- While you take tacrolimus capsules 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.

What are the possible side effects of tacrolimus capsules?

Tacrolimus capsules may cause serious side effects, including:

- See **“What is the most important information I should know about tacrolimus capsules?”**
- **problems from medicine errors.** People who take tacrolimus capsules have sometimes been given the wrong type of tacrolimus product. **Tacrolimus extended-release medicines are not the same as tacrolimus capsules** and cannot be substituted for each other. **Check your tacrolimus capsules when you get a new prescription and before you take it to make sure you have received tacrolimus capsules.**
- 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. Call your healthcare provider

right away if you have any symptoms of high blood sugar, including:

- o frequent urination
 - o increased thirst or hunger
 - o blurred vision
 - o confusion
 - o drowsiness
 - o loss of appetite
 - o fruity smell on your breath
 - o nausea, vomiting, or stomach pain
- **kidney problems.** Kidney problems are a serious and common side effect of tacrolimus capsules. Your healthcare provider may do blood tests to check your kidney function while you take tacrolimus capsules.
 - **nervous system problems.** Nervous system problems are a serious and common side effect of tacrolimus capsules. Call your healthcare provider right away if you get any of these symptoms while taking tacrolimus capsules. These could be signs of a serious nervous system problem:

- o headache
- o confusion
- o seizures
- o changes in your vision
- o changes in behavior
- o coma
- o tremors
- o 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.
- **high blood pressure.** High blood pressure is a serious and common side effect of tacrolimus capsules. Your healthcare provider will monitor your blood pressure while you take tacrolimus capsules 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:

- o shortness of breath
- o chest pain
- o feel lightheaded
- o 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 in people who have received a kidney, liver, or heart transplant are:

- infections in general, including
- swelling of the hands, legs, ankles, or

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

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. For more information, ask your healthcare provider 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 tacrolimus capsules?

Tacrolimus capsules

- Store tacrolimus capsules at room temperature between 20° to 25°C (68° to 77°F).

Keep tacrolimus capsules and all medicines out of the reach of children.

General information about the safe and effective use of tacrolimus capsules.

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

What are the ingredients in tacrolimus capsules?

Active ingredient: tacrolimus

Inactive ingredients:

Tacrolimus capsules: anhydrous lactose, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, gelatin, hypromellose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate, titanium dioxide and yellow iron oxide.

The 0.5 mg capsules also contain D&C Red No. 28, D&C Yellow No. 10 and FD&C Red No. 40, the 1 mg capsules also contain FD&C Blue No. 1 and FD&C Red No. 3 and the 5 mg capsules also contain D&C Red No. 33, D&C Red No. 28 and D&C Yellow No. 10. In addition, the black imprinting ink contains black iron oxide, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake,

FD&C Red No. 40 Aluminum Lake, propylene glycol and shellac glaze.

Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

The brands listed are trademarks of their respective owners.

For more information, call Mylan at 1-877-446-3679 (1-877-4-INFO-RX).

Additional pediatric use information is approved for Astellas Pharma US, Inc.'s Prograf (tacrolimus) products. However, due to Astellas Pharma US, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:

Mylan Pharmaceuticals Inc.

Morgantown, WV 26505 U.S.A.

Manufactured by:

Haupt Pharma Amareg GmbH

Donaustauer Strasse 378

Regensburg, Bayern, 93055, Germany

Revised: 5/2024

HPT:TACR:R2ppb/HPT:PL:TACR:R2ppb

PRINCIPAL DISPLAY PANEL - 0.5 mg

NDC 0378-2045-01

Tacrolimus

Capsules, USP

0.5 mg

Rx only 100 Capsules

Each capsule contains:

Tacrolimus, USP 0.5 mg

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

Keep container tightly closed.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F).

[See USP Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

Manufactured for:

Mylan Pharmaceuticals Inc.

Morgantown, WV 26505 U.S.A.