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Tacrolimus

pronounced as (ta kroe' li mus)

IMPORTANT WARNING:

Tacrolimus should only be given under the supervision of a doctor who is experienced in treating people who have had an organ transplant and in prescribing medications that decrease the activity of the immune system.

Tacrolimus decreases the activity of your immune system. This may increase the risk that you will get a serious infection. If you experience any of the following symptoms, call your doctor immediately: sore throat; cough; fever; extreme tiredness; flu-like symptoms; warm, red, or painful skin; or other signs of infection.

When your immune system is not working normally, there may be a greater risk that you will develop cancer, especially lymphoma (a type of cancer that begins in the cells of the immune system). The longer you take tacrolimus or other medications that decrease the activity of the immune system, and the higher your doses of these medications, the more this risk may increase. If you experience any of the following symptoms of lymphoma, call your doctor immediately: swollen lymph nodes in the neck, armpits, or groin; weight loss; fever; night sweats; excessive tiredness or weakness; cough; trouble breathing; chest pain; or pain, swelling, or fullness in the stomach area.

Studies have shown that women who received a liver transplant and were taking tacrolimus extended-release capsules (Astagraf XL) had an increased risk of death. Tacrolimus extended-release capsules (Astagraf XL) are not approved by the FDA to prevent rejection (attack of a transplanted organ by the immune system of a person receiving the organ) of a liver transplant.

Talk to your doctor about the risks of taking tacrolimus.

Why is this medication prescribed?

Tacrolimus (Astagraf XL, Envarsus XR, Prograf) is used along with other medications to prevent rejection (attack of a transplanted organ by the immune system of a person receiving the organ) in people who have received a kidney transplant. Tacrolimus (Prograf) is also used along with other medications to prevent rejection in people who have received a liver, lung, or heart transplant. Tacrolimus is in a class of

medications called immunosuppressants. It works by decreasing the activity of the immune system to prevent it from attacking the transplanted organ.

How should this medicine be used?

Tacrolimus comes as a capsule, granules for oral suspension (to be mixed with liquid), an extended-release (long acting) capsule, and an extended-release tablet to take by mouth. The immediate-release capsules (Prograf) and oral suspension (Prograf) are usually taken twice a day (12 hours apart). You may take the immediate-release capsules and oral suspension either with or without food, but be sure to take it the same way each time. The extended-release capsules (Astagraf XL) or extended-release tablets (Envarsus XR) are usually taken every morning on an empty stomach at least 1 hour before or breakfast or at least 2 hours after breakfast. Take tacrolimus at the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take tacrolimus exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking the granules for oral suspension, you will need to mix it with room temperature water before use. Place 1 to 2 tablespoons (15 to 30 milliliters) of water into a cup containing the granules. Mix the contents and then immediately take the mixture by mouth from the cup or with an oral syringe; do not save the mixture for a later time. The granules will not completely dissolve. If any of the mixture remains, add 1 to 2 tablespoons (15 to 30 milliliters) of water to the mixture and immediately take it.

Swallow the extended-release capsules and extended-release tablets whole with water; do not split, chew, or crush them. Do not open the immediate-release capsules,

Your doctor will monitor you carefully and adjust your dose as needed. Talk to your doctor often about how you are feeling during your treatment. Ask your doctor if you have any questions about how much tacrolimus you should take.

Different tacrolimus products release the medication differently in your body and cannot be used interchangeably. Only take the tacrolimus product prescribed by your doctor and do not switch to a different tacrolimus product unless your doctor says that you should.

Tacrolimus can only prevent rejection of your transplant as long as you are taking the medication. Continue to take tacrolimus even if you feel well. Do not stop taking tacrolimus without talking to your doctor.

Other uses for this medicine

Tacrolimus is also sometimes used to treat fistulizing Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, fever, and the formation of abnormal tunnels connecting the digestive tract to other organs or the skin). Talk to your doctor about the risks of using this medication to treat your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking tacrolimus,

- tell your doctor and pharmacist if you are allergic to tacrolimus, any other medications, or any of the other ingredients in tacrolimus products. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: amiodarone (Nexterone, Pacerone); amphotericin B (Abelcet, Ambisome); angiotensin-converting enzyme (ACE) inhibitors such as benazepril (Lotensin, in Lotrel), captopril, enalapril (Vasotec, in Vaseretic), fosinopril, lisinopril (in Prinzide, in Zestoretic), moexipril (Univasc, in Uniretic), perindopril (Aceon, in Prestalia), quinapril (Accupril, in Quinaretic), ramipril (Altace), ortrandolapril (in Tarka); antacids containing magnesium and aluminum hydroxide (Maalox); certain antibiotics including aminoglycosides such as amikacin, gentamicin, neomycin (Neo-Fradin), streptomycin, and tobramycin (Tobi), and macrolides such as clarithromycin (Biaxin), erythromycin (EES, E-Mycin, Erythrocin), and troleandomycin (TAO; not available in the US); antifungal medications such as clotrimazole (Lotrimin, Mycelex), fluconazole (Diflucan), itraconazole (Onmel, Sporanox), ketoconazole, posaconazole (Noxafil), and voriconazole (Vfend); angiotensin receptor blockers (ARBs) such as azilsartan (Edarbi, in Edarbyclor), candesartan (Atacand, in Atacand HCT), eprosartan (Teveten), irbesartan (Avapro, in Avalide), losartan (Cozaar, in Hyzaar), olmesartan (Benicar, in Azor, in Benicar HCT, in Tribenzor), telmisartan (Micardis, in Micardis HCT, in Twynsta); boceprevir (Victrelis; no longer available in U.S.); calcium channel blockers such as diltiazem (Cardizem), nifedipine, nifedipine (Adalat, Procardia), and verapamil (Calan, Verelan, in Tarka); caspofungin (Cancidas); chloramphenicol; cimetidine (Tagamet); cisapride (Propulsid; not available in the U.S.); cisplatin; danazol; certain diuretics ('water pills'); ganciclovir (Valcyte); certain hormonal contraceptives (birth control pills, patches, rings, inserts, or injections); certain medications for HIV such as didanosine (Videx); indinavir (Crixivan), lamivudine (Epivir); nelfinavir (Viracept), ritonavir (Norvir), stavudine (Zerit), and zidovudine (Retrovir) lansoprazole (Prevacid); methylprednisolone (Medrol); metoclopramide (Reglan); mycophenolate (Cellcept); nefazodone; omeprazole (Prilosec); prednisone; rifabutin (Mycobutin); rifampin (Rifadin, Rimactane); certain medications for seizures such as carbamazepine (Tegretol, Teril), phenobarbital, and phenytoin (Dilantin, Phenytek); sirolimus (Rapamune), and telaprevir (Incivek; no longer available in U.S.). Your doctor may need to change the doses of your medications or monitor you more carefully for side effects. Many other medications may also interact with tacrolimus, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you are taking or have recently stopped taking cyclosporine (Gengraf, Neoral, Sandimmune). If you were taking cyclosporine, your doctor will probably tell you not to start taking tacrolimus until 24 hours after you took your last dose of cyclosporine. If you stop taking tacrolimus, your doctor will also tell you to wait 24 hours before starting to take cyclosporine.
- tell your doctor and pharmacist what herbal products you are taking, especially St. John's wort or schisandra sphenanthera extracts. Do not take these herbal products while taking tacrolimus.
- tell your doctor if you have or have ever had long QT syndrome (an inherited condition in which a person is more likely to have QT prolongation) low levels of potassium, calcium, or magnesium in your blood, an irregular heartbeat, high cholesterol levels, cystic fibrosis (an inborn disease that causes the body to produce thick, sticky mucus that may clog the pancreas, the lungs, and other parts of the body), heart, kidney, or liver disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you or your partner are able to become pregnant, use effective birth control before and during treatment with tacrolimus. If you become pregnant while taking tacrolimus, call your doctor. Tacrolimus may harm the fetus.

- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking tacrolimus.
- you should know that taking tacrolimus may increase the risk that you will develop skin cancer. Protect yourself from skin cancer by avoiding unnecessary or prolonged exposure to sunlight or ultraviolet light (tanning beds) and wearing protective clothing, sunglasses, and sunscreen with a high skin protection factor (SPF).
- do not drink alcoholic beverages while you are taking tacrolimus extended-release capsules or extended-release tablets. Alcohol can make the side effects from tacrolimus worse.
- you should know that tacrolimus may cause high blood pressure. Your doctor will monitor your blood pressure carefully, and may prescribe medication to treat high blood pressure if it develops.
- you should know that there is a risk that you will develop diabetes during your treatment with tacrolimus. African American and Hispanic patients who have had kidney transplants have an especially high risk of developing diabetes during their treatment with tacrolimus. Tell your doctor if you or anyone in your family has or has ever had diabetes. If you experience any of the following symptoms, call your doctor immediately: excessive thirst; excessive hunger; frequent urination; blurred vision or confusion.
- do not have any vaccinations without talking to your doctor.

What special dietary instructions should I follow?

Avoid eating grapefruit or drinking grapefruit juice while taking tacrolimus.

What should I do if I forget a dose?

If the immediate-release capsule or oral suspension dose is missed, take it as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If the extended-release capsule dose is missed, take the dose if it is within 14 hours after missing the dose. However, if it is more than 14 hours, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If the extended-release tablet dose is missed, take the dose if it is within 15 hours after missing the dose. However, if it is more than 15 hours, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Tacrolimus may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- diarrhea
- constipation
- nausea
- vomiting

- heartburn
- stomach pain
- loss of appetite
- difficulty falling asleep or staying asleep
- dizziness
- weakness
- back or joint pain
- burning, numbness, pain, or tingling in the hands or feet

Some side effects can be serious. If you experience any of the following symptoms, or those mentioned in the IMPORTANT WARNING section, call your doctor immediately:

- decreased urination
- pain or burning on urination
- shortness of breath, hives, rash, or itching
- pale skin, shortness of breath, or fast heartbeat
- tiredness; weight gain; swelling of the arms, hands, feet, ankles, or lower legs; or shortness of breath
- unusual bleeding or bruising
- seizures, vision changes, headache, confusion, or uncontrollable shaking of a part of the body
- coma (loss of consciousness for a period of time)

Tacrolimus may cause other side effects. Call your doctor if you have any unusual problems while you are taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- hives
- sleepiness
- nausea, vomiting, and diarrhea
- uncontrollable shaking of a part of the body, headache, confusion, imbalance, and extreme tiredness
- swelling of arms or legs
- fever or other signs of infection

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests before and during your treatment to check your body's response to tacrolimus.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Astagraf XL[®]
- Envarsus XR[®]
- Prograf[®]

Other names

- FK 506

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