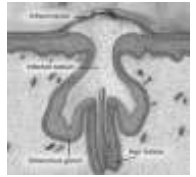


Rx TACROLIMUS

(Tacrolimus is a drug that suppresses the immune system)



GENERIC NAME: tacrolimus

DRUG CLASS AND MECHANISM

Tacrolimus is a drug that suppresses the immune system and is used to prevent rejection of transplanted organs. Tacrolimus accomplishes its immune-suppressing effecting by inhibiting an enzyme (calcineurin) crucial for the multiplication of T-cells, cells that are vital to the immune process. The use of oral tacrolimus allows transplantation specialists to reduce the dose of steroids which are also used to prevent rejection. This "steroid-sparing effect" is important because of the many side effects that can occur when larger doses of steroids are used for a long period of time. Tacrolimus was approved by the FDA in April, 1994 for liver transplantation and also has been used in patients for heart, kidney, small bowel, and bone marrow transplantation.

GENERIC AVAILABLE: No

PRESCRIPTION: Yes

PREPARATIONS: Tacrolimus is available as 1mg and 5mg capsules. It also is available for intravenous use.

PRESCRIBED FOR: Tacrolimus is used for the prevention of rejection of transplanted organs.

DOSING

Oral tacrolimus is taken twice daily. Doses vary widely and are based on blood tests that measure the amount of tacrolimus in the body. Taking tacrolimus with food can reduce some of the abdominal pain that can occur with this medicine; however, food can reduce the amount of tacrolimus that is absorbed. This is especially true with fatty foods. Thus, tacrolimus is best taken without food. If it must be taken with food, it should be taken with non-fatty food.

DRUG INTERACTIONS

The destruction of tacrolimus by the body may be inhibited by a large number of drugs, resulting in higher blood levels of tacrolimus, and possibly increasing its side effects. Such drugs include bromocriptine (Parlodel), cimetidine (Tagamet), cisapride (Propulsid), clarithromycin (Biaxin), cyclosporine (Sandimmune; Neoral), danazol (Danocrine), diltiazem (Cardizem; Tiazac), erythromycin, fluconazole (Diflucan), itraconazole (Sporanox), ketoconazole (Nizoral), metoclopramide (Reglan), methylprednisolone (Medrol), nicardipine (Cardene), troleandomycin (Tao), and verapamil (Calan; Isoptin; Verelan; Covera-HS). Grapefruit juice also may have a similar effect on tacrolimus and should be avoided.

Other drugs can stimulate the break-down of tacrolimus, decreasing its blood concentration and possibly reducing its effectiveness. Such drugs include carbamazepine (Tegretol), nifedipine (Procardia; Adalat); phenobarbital, phenytoin (Dilantin), rifabutin, and rifampin,

Live virus vaccines should be avoided while receiving tacrolimus or any other medicine that suppresses the immune system since the vaccines may be less effective.

Since tacrolimus can cause hyperkalemia (high potassium in the blood), the use of tacrolimus with diuretics that also cause retention of potassium is not recommended. Such diuretics include triamterene (found in Dyazide and Maxzide), amiloride (found in Moduretic), and spironolactone (Aldactone).

Aluminum hydroxide, which is found in many antacids, binds tacrolimus in the stomach. Aluminum-containing antacids should not be taken with tacrolimus.

USES

Tacrolimus is used to prevent the body from rejecting a transplanted organ.

OTHER USES

This medication may also be used for other purposes as determined by your doctor.

HOW TO USE

Take this medication by mouth exactly as prescribed, usually every 12 hours. It is best taken on an empty stomach 1 hour before or 2 hours after a meal. If stomach upset occurs, you may take this medication with food; however, this

may decrease the amount of tacrolimus absorbed into your bloodstream. If you take this on an empty stomach, always take it on an empty stomach. If you take it with food, always take it with food. Consult your doctor for more details (since your doctor will be monitoring the amount of this drug in your blood). Your dose may be adjusted based on your response, tolerance, and blood tests (tacrolimus trough blood levels). Follow dosing instructions closely. Do not increase the dose or take this more often than directed since the chance of side effects will be increased. Continue taking this medication as directed even if you are feeling well. Do not eat grapefruit or drink grapefruit juice unless your doctor instructs you otherwise.

SIDE EFFECTS

Tremor, headache, diarrhea, nausea, increased blood pressure, trouble sleeping or tingling of the hands or feet may occur. If any of these effects persist or worsen, notify your doctor promptly. Notify your doctor promptly if you develop: vomiting, dizziness, anxiety, fever, chills, weakness, vision changes, chest pain, easy bruising or bleeding, swelling of the feet or ankles. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: fainting, irregular heartbeat. In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Tell your doctor if you have: kidney disease, liver disease, high blood pressure, diabetes, any allergies. This medication is not recommended for use if you have the following medical conditions: heart disease (e.g., QT prolongation). This medication is not recommended for use during pregnancy or while breastfeeding. Discuss the risks and benefits with your doctor.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include chest pain, hand tremors, or decrease in amount of urine.

MISSED DOSE

Take this medication as directed. If you miss a dose, take it as soon as remembered; do not take it if it is near the time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

STORAGE

Store this medication at room temperature between 59 and 86 degrees F (15 to 30 degrees C) away from heat and light. Do not store in the bathroom. Keep this and all medications out of the reach of children.

WARNING

Tacrolimus may leave you less able to fight infection and could also cause tumors. This medication must be used in an appropriate setting. Notify your doctor immediately if you develop signs of infection (such as persistent sore throat or fever), or unusual growths.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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