

## Tacrolimus (Prograf)

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### About This Drug

Tacrolimus is used to decrease the risk of rejection of a transplanted organ. It is given orally (by mouth) or by the vein (IV).

### Possible Side Effects

- Decrease in white blood cells and red blood cells. This may raise your risk of infection and make you feel tired and weak.
- Fluid accumulating around your heart
- Nausea
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Swelling in your legs, ankles, and/or feet
- Fever
- Risk of infections such as cytomegalovirus (CMV) infection. CMV is a common virus which can cause more severe infection in patients with compromised immune systems.
- Infection
- Urinary tract infection
- Increase in your cholesterol levels
- Electrolyte changes
- Blood sugar levels may change
- Numbness, tingling or a sensation of pins and needles in your arms, hands, legs, or feet
- Headache
- Tremors
- Trouble sleeping
- Changes in your kidney function
- Inflammation of your airway
- High blood pressure

**Note:** Each of the side effects above was reported in 15% or greater of patients treated with tacrolimus. Not all possible side effects are included above.

## Warnings and Precautions

- This drug may raise your risk of getting a second cancer, such as lymphoma, skin cancer, and other cancers.
- Severe and life-threatening infections
- Blood sugar levels may change, and you may develop diabetes.
- Severe changes in your kidney function, which can cause kidney failure.
- Changes in your central nervous system can happen which can be life-threatening. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have hallucinations (see or hear things that are not there), trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, seizures or coma
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your doctor know right away.**
- Severe increased level of potassium in your blood
- Severe high blood pressure
- When tacrolimus is given by the vein (IV), allergic reactions can happen, including anaphylaxis. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Changes in your heart function and abnormal electrocardiogram (EKG/ECG)
- Severe decrease in red blood cells which can cause you to have severe anemia.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

## Important Information

- Tacrolimus capsules and granules are types of immediate-release medicine and they are not the same as extended-release tablets or extended-release capsules. Your doctor should decide what medicine is right for you.
- Talk to your doctor before receiving any vaccinations during your treatment. Some vaccinations are not recommended while receiving tacrolimus.
- Let your doctor know right away if you think you may be pregnant and report any pregnancy at 1-877-955-6877 or go to <https://www.transplantpregnancyregistry.org/>.

## How to Take Your Medication

- Inspect your medicine when you receive a new prescription. If the appearance of the capsule is not the same as usual, or if dose instructions have changed, contact your doctor to make sure that you have the right medicine.



- The capsules and/or granules can be taken with or without food, at approximately the same time each day. Take each dose the same way, either with or without food. This helps keep the levels of tacrolimus in your blood more stable.
- Your doctor may change your dose based on the result of blood work. Do not stop taking or change your dose of tacrolimus without talking to your doctor.
- **Capsules only:** Swallow the medicine whole, do not open or crush capsules.
- **Granules only:** To prepare the dose, empty the entire contents of each granules packet that is needed for the dose into a glass cup. Check for any remaining granules in the packet(s) and empty these into the cup. Add 1 to 2 tablespoons (15 to 30 milliliters) of room temperature drinking water to the cup (granules will not completely dissolve). Mix well and take the entire contents of the cup immediately after preparing. Refill the glass cup with 15 to 30 milliliters of water, swirl to mix up any remaining granules and swallow contents of the cup. Do not save the prepared granules for a later time.
- **Missed dose:** If you vomit or miss a dose, contact your doctor for further instructions. Do not take 2 doses at the same time or extra doses.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- If you get any of the content of a broken capsules or prepared granules on your skin or in your eyes, you should wash the area of the skin well with soap and water right away. Wash your eyes with flowing water and call your doctor. Call your doctor if you get a skin reaction
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store the capsules and granules in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop diarrhea and/or constipation.



- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- Avoid sun exposure and apply sunscreen routinely when outdoors. Cover up when you are out in the sun. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.

## Food and Drug Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of tacrolimus in your body which could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with tacrolimus. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking tacrolimus as this may lower the levels of the drug in your body, which can make it less effective.

## When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Tiredness that interferes with your daily activities
- Trouble falling or staying asleep
- Feeling dizzy or lightheaded
- Extreme tiredness, agitation, confusion, and/or coma
- Hallucinations
- Trouble understanding or speaking
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Headache that does not go away
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**



- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Trouble breathing
- Chest pain, especially when you lean forward or take deep breaths
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling in your legs, ankles, and/or feet
- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of a urinary tract infection such as burning or pain when you pass urine, difficulty urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back.
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Numbness, tingling, pins, and needles, or pain your arms, hands, legs, or feet
- Decreased or very dark urine
- If you think you may be pregnant or may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential and men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** This drug can pass into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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