

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Tacrolimus, Ophthalmic

(*ta-kroe-li-mus*)

Description:

Immunosuppressive Lacromimetic Agent

Other Names for this Medication:

Protopic®, Prograf®

Common Dosage Forms:

Veterinary: None. **Human:** Tacrolimus is manufactured as an injection and a topical ointment for humans, but a dosage form for the eye is not currently manufactured. Tacrolimus ophthalmic ointments and solutions may be made (compounded) by qualified professionals.

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- ▶ Tacrolimus is a lifelong medication that must be used twice daily. Missed doses may cause return of dry eye. It may take days to weeks to notice improvement. Do not stop the medication without asking your veterinarian.
- ▶ **Wear gloves when applying this medication. Pregnant women should NOT handle this drug.** Use proper administration techniques to avoid contamination of the medication. Keep cap tightly closed when not in use.
- ▶ Wait 5 minutes after applying this medication before applying any other medications to the eye.
- ▶ Store at room temperature away from moisture and sunlight; do not freeze.
- ▶ Do not use if the color changes, if it becomes cloudy, or if particles are seen in solutions.
- ▶ Protopic® ointment should *not* be used in the eye. An ophthalmic ointment or solution should be made (compounded) by a qualified professional.

How is this medication useful?

Tacrolimus is useful in treating dry eye (keratoconjunctivitis sicca) and CSK (chronic superficial keratitis) in dogs. It may also be useful in treating immune-mediated keratitis and pannus in horses and dogs. Veterinarians have also used tacrolimus to treat a severe immune-mediated ear condition called, necrotizing otitis externa. The FDA (U.S. Food & Drug Administration) has approved this drug for use in humans but not in animals.

The FDA allows veterinarians to prescribe and use human products containing this drug in animals in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- ▶ Other drugs can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including other eye medications, vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- ▶ Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.
- ▶ If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn't work.
- ▶ If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- ▶ Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication takes several doses before you will see any effect. The medication's full effects may not be evident until your animal has taken it consistently for several weeks, but you will see a gradual improvement of your animal's clinical signs until the medication becomes fully effective. The effects of this medication are moderate in duration, meaning they may last for a few days.

When should this medication not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug **SHOULD NOT** be used in patients:

- ▶ That are allergic to it or drugs like it.
- ▶ That have eye infections caused by a virus (herpes) or a fungus.

This drug should be used **WITH CAUTION** in patients:

- ▶ That are pregnant or nursing.

If your animal matches any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

Side effects that usually are not serious include:

- ▶ Mild burning, stinging, irritation, or redness.
- ▶ Eyelid spasm.
- ▶ Loss of hair around the eye.

If any of these signs are severe, worsen, or continue to be a problem, contact your veterinarian.

Side effects that may be serious or indicate a serious problem:

- ▶ Difficulty breathing or swelling of the throat indicates a severe allergic reaction to this drug.
- ▶ Weakness or tiredness indicating blood problems including blood cancer.

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

When used as an eye medication, overdoses are not likely. But side effects or toxic effects could occur if your animal eats the medication. If this happens contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **ASPCA Animal Poison Control Center** (888-426-4435) and **Pet Poison HELPLINE** (855-764-7661); a consultation fee may be charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- ▶ Administer this drug to your animal's eye in the exact amount that your veterinarian has prescribed.
- ▶ Wash your hands before administering this medication.
- ▶ Do not touch the dropper tip or allow it to touch your animal's eye or any other surface to prevent contamination.
- ▶ If any residue is left on your animal's face after giving the eye drops, gently wipe it off with a damp cloth or tissue.
- ▶ If you are administering more than one eye medication to your animal, wait 5 minutes between each medication before giving the next one. Use eye drops before eye ointments to allow the drops to absorb into the eye.
- ▶ If you are using this medication as an eye solution for your horse, your veterinarian may have implanted a special eye catheter (subpalpebral lavage or SPL catheter). Use this catheter exactly as your veterinarian has prescribed and only use air to flush the medications to the eye after injecting into the catheter.
- ▶ If you are having difficulty applying the medication or your animal does not accept the treatment, contact your veterinarian or pharmacist for tips to help with administration and reducing the stress of medication time.
- ▶ This medication can be given for various lengths of time. Be sure you understand how long the veterinarian wants you to continue giving this medication.
- ▶ Prescription refills may be necessary before the therapy will be complete. Before stopping this medication, talk to your veterinarian, as there may be important reasons to continue its use.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember, but if it is close to the time for the next dose, skip the dose you missed and give it at the next scheduled time. After that, return to the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- ▶ Store this medication in the original prescription bottle or an approved dosage reminder container at room temperature and protected from light.
- ▶ If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- ▶ Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other animals?

- ▶ **Pregnant women should NOT handle this drug.**
- ▶ **Tacrolimus drug can cause serious adverse effects in people or animals that are exposed to it. Use of disposable gloves is strongly advised when handling this medication.** Dispose of used gloves in the trash immediately after use.
- ▶ Do not allow this medicine to come into contact with your skin, eyes, or mucous membrane (eg, nasal passages, mouth).
- ▶ This drug can also be found in the treated animal's saliva, urine, or feces. Wear gloves when disposing of cat litter or dog droppings or cleaning up urine spills. Do not let treated animals lick human skin. If skin exposure occurs, the area should be washed thoroughly with soap and water.

How should I dispose of this medication if I don't use it all?

- ▶ Do not flush this medication down the toilet or wash it down the sink. If a community drug "take-back" program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- ▶ Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.

Special Instructions

Topical Therapy Tacrolimus (Protopic®) is a topical calcineurin inhibitor. Its mechanism of action (i.e. inhibition of cytokine production via inhibition of gene transcription in T-cells) is similar to that of cyclosporine. Tacrolimus is 10-100 times more potent than cyclosporine. Tacrolimus is applied topically as a thin film to affected areas q 12-24 hrs. Tacrolimus can be used alone if clinical signs are mild and the dog accepts topical therapy. In one study, 50% (5/10) of dogs had complete resolution after 16 weeks of tacrolimus treatment. Tacrolimus can also be used alone as maintenance therapy to minimize recurrence in dogs that are in remission after cyclosporine therapy. Administer tacrolimus for 4 weeks beyond clinical resolution and then taper to q 48 hrs, then twice weekly, and eventually less often. It can be administered indefinitely as maintenance or preventive therapy. Tacrolimus can initially cause erythema and irritation at the site of application in some dogs. These side effects may resolve within a few days, and may be diminished by decreasing the frequency of application. Although tacrolimus formulations are available in 0.03% strength in cutaneous and compounded ophthalmic products, dermatologic conditions are most commonly treated with the 0.1% cutaneous formulation (Protopic®). Clients should wear gloves when applying the medication to minimize absorption through their skin. Cancer has been observed in some humans receiving tacrolimus. However, no known association between cancer and topical tacrolimus administration exists in dogs.