

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]

Cyclosporine (Dogs)

(*syeh-kloe-spor-eeen*)

Description:

Immunosuppressant

Other Names for this Medication:

Ciclosporin, Atopica[®], Sandimmune[®], Neoral[®]

Common Dosage Forms:

Veterinary (Dogs): 10 mg, 25 mg, 50 mg, & 100 mg soft-gelatin oral capsules. **Human:** 25 mg, 50 mg, & 100 mg soft-gelatin oral capsules; 100 mg/mL oral liquid. Note: There are different kinds of cyclosporine that have the same dosage forms. They are NOT interchangeable as they can be absorbed differently. Compounded products may also be available.

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

- ▶ Give on empty stomach (1 hour before or 2 hours after feeding). If your animal vomits or acts sick after receiving this drug on an empty stomach, try giving the next dose with food or a small treat. If vomiting continues, contact your veterinarian.
- ▶ May take up to 2 weeks to see if the drug is working. Cyclosporine level blood tests may be done if your animal is taking this medicine for immunosuppression.
- ▶ Vomiting, reduced appetite, and diarrhea are the most common side effects. These signs usually get better on their own, but if they are severe or persistent, contact your veterinarian.
- ▶ Contact your veterinarian immediately if you notice signs indicating an infection (eg, fever, low energy, poor appetite).
- ▶ Pregnant women should handle this drug very carefully.

How is this medication useful?

Cyclosporine is used to prevent rejection of transplanted organs, treat skin and blood conditions that are caused by over active immune systems, and is also useful in allowing healing of sores around the anus (ie, perianal fistulas) that do not respond to other treatments. The FDA (U.S. Food & Drug Administration) has approved a cyclosporine product (Atopica[®]) for use in dogs to treat atopic

dermatitis. The FDA (U.S. Food & Drug Administration) has also approved several cyclosporine products for use in humans, but these are not officially approved for use in animals. The FDA allows veterinarians to prescribe products containing this drug in different species or for other conditions 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 dog. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- ▶ Other drugs can interact with cyclosporine, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your dog, including the amount and time you give each.
- ▶ Tell your veterinarian about any conditions or diseases your dog may have now or has had in the past.
- ▶ If your dog 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 dog 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 dog 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 short-lived, meaning they will stop working within 24 hours, although the benefits may be prolonged if your animal has decreased kidney and/or liver function.

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 dogs:

- ▶ That are allergic to it.
- ▶ With suspected cancer or a history of cancer.

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

- ▶ That have an infection.
- ▶ With liver or kidney disease.
- ▶ That are pregnant or nursing. Cyclosporine has caused birth defects in rodents. It is not known if it is safe for nursing offspring if the mother is getting the drug.
- ▶ With a seizure disorder (eg, epilepsy).
- ▶ That are under 4 lb (2 kg) body weight or younger than 6 months old as safety and effectiveness have not been established (Atopica® label).

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

What are the side effects of this medication?

Side effects are usually mild and often get better with time.

Common but not serious side effects include:

- ▶ Vomiting, reduced appetite, diarrhea. These effects are seen in approximately 1 in 3 dogs usually in the first 1-2 days after starting the drug and often improve over time. Your veterinarian may prescribe anti-vomiting medications or temporarily stop the drug if these occur.
- ▶ Overgrowth of gums (gingival hyperplasia) and skin growths (both are rare).
- ▶ Lethargy (tiredness, lack of energy).

You don't have to be overly concerned if you see any of these signs unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

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

- ▶ Infection. Cyclosporine can weaken your dog's immune system. Watch for signs of infection such as fever (103°F-104°F), tiredness or lack of energy, sneezing, coughing, poor appetite, or runny eyes.

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

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

Overdoses of cyclosporine can cause serious effects. If you witness or suspect an overdose, 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 is 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.

- ▶ The drug should be given at least 1 hour before or 2 hours after a meal, but if your animal vomits or acts sick after getting it on an empty stomach, give with a small amount of food or small treat to see if this helps. If vomiting continues, contact your veterinarian.
- ▶ Liquid forms of this medication must be measured carefully. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes.
- ▶ Most animals do not like the taste of cyclosporine. If you have difficulty getting your dog to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time for both you and your dog.
- ▶ Patients are usually on this medication for an extended period, often for the rest of their lives. Give this medication according to the label's instructions and obtain refills as needed. 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. Don't give it more than once per day if you regularly give the drug once a day.

How should I store this medication?

- ▶ When using the approved product for dogs (Atopica®), store in the original container at room temperature (59°F-77°F).
- ▶ 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 and people who are allergic to this drug should be very careful not to accidentally take it. Because this drug has a higher risk for causing birth defects, pregnant women should wear disposable gloves when giving doses or handling the drug and avoid inhaling any dust from split or crushed tablets.

Skin or eyes exposed to powder or liquids containing the drug should immediately be washed or rinsed off thoroughly.

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?

- ▶ Because cyclosporine therapy can be expensive, veterinarians may prescribe another drug (eg, ketoconazole) that can increase the amount of cyclosporine in the blood and allow lower dosages to be given. This treatment plan must be done under the close supervision of your veterinarian.
- ▶ There are different forms of cyclosporine and doses for them may not be the same. Check with your veterinarian or pharmacist before changing brands or dosage forms to be sure that the dosage does not change.

- ▶ Cyclosporine may keep vaccines from working properly. Your dog should receive killed virus vaccines and not modified live virus vaccines while on cyclosporine.
- ▶ If your animal is taking cyclosporine for immunosuppression, your veterinarian may need to perform blood tests to check cyclosporine levels in your dog's blood. Do not miss these important follow-up visits.
- ▶ 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:
