

## 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]

## Spinosad

(*spin-oh-sad*)

### Description:

Flea Adulticide

### Other Names for this Medication:

Comfortis®

### Common Dosage Forms:

**Veterinary:** Chewable tablets: 90 mg, 140 mg, 270 mg, 560 mg, 810 mg, & 1620 mg. **Human:** None as oral products; topical forms are 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

- ▶ Spinosad is an oral tablet given monthly that kills adult fleas on dogs and cats; it begins to kill fleas 30 minutes after dosing. This product does not kill ticks.
- ▶ Give medication with food.
- ▶ When used as directed on the label, this medication appears safe.
- ▶ Product can be harmful to wildlife, so dispose of unused drugs carefully.
- ▶ Keep chewable tablets well out of reach of children and animals.

### How is this medication useful?

Spinosad is given by mouth to dogs and cats to prevent and treat flea infestations. The FDA (U.S. Food & Drug Administration) has approved this drug to prevent and treat flea infestations for 1 month in dogs at least 14 weeks of age that weigh at least 3.3 pounds and in cats that are at least 14 weeks of age and weigh at least 2 pounds. The FDA allows veterinarians to prescribe and use 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 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 drug, so be sure to tell your veterinarian and pharmacist what medications (including 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?**

Fleas will begin to die within 4 to 8 hours. Your animal's clinical signs should begin to improve after that time. The effects of this medication are long-lived, meaning they may last for multiple (ie, 4 to 6) weeks, although they 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 patients:

- ▶ That are allergic to it.

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

- ▶ Animals with a seizure disorder (eg, epilepsy).
- ▶ Cats: Less than 14 weeks of age or that weigh less than 2 pounds; safe use in these animals has not been determined.
- ▶ Dogs: Less than 14 weeks of age or that weigh less than 3.3 pounds; safe use in these animals has not been determined.
- ▶ Animals receiving higher doses of a drug called ivermectin.

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?**

Spinosad is normally tolerated well and side effects are rare.

#### ***Common but not serious side effects include:***

- ▶ Vomiting, diarrhea.
- ▶ Excessive salivation (drooling).
- ▶ Itching.
- ▶ Trembling.
- ▶ Lack of energy.
- ▶ Reduced appetite.

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:***

- ▶ Stumbling, incoordination, weakness.
- ▶ Seizures (convulsions).

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?**

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 **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center**

(888-426-4435); 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.

- ▶ Spinosad is given monthly when used for flea control.
- ▶ Dogs usually willingly eat the chewable tablets when offered them just before feeding, and cats willingly take before or after feeding. Alternatively, tablets can be mixed in food or given like other tablet medications.
- ▶ If vomiting occurs within an hour of administration, you can give another full dose.
- ▶ Compounded liquid forms of this medication must be measured carefully. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes.
- ▶ If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time.
- ▶ This medication can be given for various lengths of time. Be sure you understand how long your 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, and then wait the amount of time between doses recommended by your veterinarian before giving another dose. Do not double-up or give extra doses.

### **How should I store this medication?**

- ▶ Store this medication in the original prescription container or an approved dosage reminder container (ie, pill minder) 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?**

There are no specific precautions required when handling this medication unless you are allergic to it. Wash your hands after handling any medication.

### **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?**

- ▶ Treatment with spinosad may begin at any time of the year but should preferably start 1 month before fleas become active and continue monthly through the end of flea season. In areas where fleas are common, year-round, monthly treatment should continue year round without stopping.
- ▶ To reduce the chance of flea reinfestation, all animals in the household must be treated with an approved flea protection product.
- ▶ 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**

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