

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]

Fluocinolone Acetonide & Dimethyl Sulfoxide (DMSO), Topical Solution

(*floo-oh-sin-oh-lone* and *dye-meth-el sul-fox-ide*)

Description: Topical ear treatment

Other Names for this Medication: Synotic®

Common Dosage Forms: Veterinary: Fluocinolone acetonide 0.01% & DMSO 60% solution in 8 mL & 60 mL bottles. **Human:** None.

This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- ▶ Treats inflamed and itchy ears.
- ▶ Do not allow your animal to lick the medication (eg, during grooming).
- ▶ Avoid contact with eyes.
- ▶ Use is typically limited to 14 days.
- ▶ Allow the medicine to dry before using other ear treatments.
- ▶ Can cause garlic- or oyster-like bad breath.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved the combination of fluocinolone acetonide and dimethyl sulfoxide for use in dogs to relieve itching and inflammation caused by ear problems. The FDA allows veterinarians to prescribe products containing these drugs in different species or for other conditions in certain situations. You and your veterinarian can discuss why this medicine 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 medicine 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 topical therapies, 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 should help your animal feel better within 1 to 2 hours. Your animal's clinical signs should improve after that time. The effects of this medication are short-lived, meaning they will stop working within 24 hours.

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

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

This medicine **SHOULD NOT** be used in animals:

- ▶ That are allergic to it.
- ▶ With a suspected or confirmed ruptured ear drum.
- ▶ That are pregnant.
- ▶ That are about to go through allergy testing.

This medicine should be used **WITH CAUTION** in patients that have:

- ▶ Sore or burned skin.
- ▶ Ear infections.

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?

In dogs, this medicine is typically well tolerated.

Side effects that usually are not serious include:

- ▶ Redness, warmth, or discomfort at the site of application.
- ▶ Odor. This medicine can cause garlic- or oyster-like breath odor. This problem goes away when the treatment is stopped.

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:

- ▶ Ears that do not respond to treatment, do not appear to be healing, or are getting worse.
- ▶ Loss of appetite, vomiting, or diarrhea.
- ▶ Sudden hearing loss.
- ▶ Progressive ear pain.
- ▶ Head tilt or walking in circles.
- ▶ Development of sores around the mouth.
- ▶ Increased thirst (eg, frequent drinking of large quantities of water) and frequent urination.
- ▶ Thinning of the skin, progressive hair loss and skin redness, increased skin tears, or infections at the application site.

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.

- ▶ Trim hair around affected areas as necessary.
- ▶ This medicine should be applied to clean ears only. Your veterinarian should show you how to clean your animal's ears.
- ▶ After applying drops to the ears, gently massage the ear flap to move the medicine down into the ear canal.

- ▶ Discuss with your veterinarian if your animal’s condition is not improving, or if problems return after treatment is complete.
- ▶ Avoid contact with your animal’s eyes, mouth, and nose.
- ▶ Administer separately from other ear treatments or medications. Allow this medicine to dry before administering other treatments or medications into the same ear(s).
- ▶ If you have difficulty with your animal and the treatment, 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, but if it is close to the time for the next 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 bottle at room temperature and protected from light.
- ▶ Bottle must be closed tightly after use.
- ▶ 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?

Do not allow this medicine to come in contact with bare skin. Wear disposable, nonpermeable (does not allow liquid to pass through) gloves when applying or handling the drug. Wash 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?

- ▶ 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.
- ▶ Do not stop giving the medication before your veterinarian recommends, even if the infection appears to have resolved. Stopping treatment early may lead to chronic infections. Your veterinarian will want to recheck your animal to make sure the infection has completely resolved. Do not miss these important follow-up visits.
- ▶ This medicine may affect allergy testing. Talk with your veterinarian about when to stop giving this medication if an allergy test is planned.

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

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| Special Instructions: <hr/> <hr/> <hr/> <hr/> |
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