

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]

Polymyxin B/Miconazole/Prednisolone Ear Drops

(*pol-lee-mix-in bee/ mye-kon-uh-zohl/pred-niss-oh-lone*)

Description:

Topical treatment for bacterial and fungal (yeast) ear infections

Other Names for this Medication:

Surolan

Common Dosage Forms:

Veterinary: polymyxin B 0.5293 mg/mL, miconazole 23 mg/mL, and prednisolone 5 mg/mL suspension in 15-mL and 30-mL bottles.

Human: None.

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

- Combination ear drop with antibacterial, antifungal, and anti-inflammatory activity
- Do not apply this medicine in your animal's ear without your veterinarian's guidance, as this medicine should not be used in animals with ruptured ear drums.
- Usually well tolerated, but pain or irritation after application is possible
- Shake bottle well before applying each dose.

How is this medication useful?

The FDA (US Food & Drug Administration) has approved this topical suspension for use in dogs with ear infections that are caused by fungi (yeast) and bacteria. This combination product contains an antibiotic (polymyxin B), an antifungal (miconazole), and a steroid anti-inflammatory (prednisolone). The FDA allows veterinarians to prescribe products containing this medication in different species or for other conditions in certain situations. You and your veterinarian can discuss why this medication 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 medicines can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including other topical medicines, 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 did not work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks for using this medicine.
- 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 start having effects within 1 to 2 hours. Your animal should start feeling better within 1 to 2 days. The effects of this medication are moderate in duration, meaning they may last for a couple of days after the last dose.

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

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

This medication **SHOULD NOT** be used in animals that:

- Are allergic to any of the ingredients.
- Have a ruptured ear drum.

What are the side effects of this medication?

This medication is typically well tolerated.

Side effects that are usually not serious include:

- Discomfort or irritation after application
- Vomiting

Contact your veterinarian if any of these signs are severe, continue to occur, or worsen over time.

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

- Reduced hearing or hearing loss
- Red blisters on the skin of the ear

Contact your veterinarian immediately if you notice any of these signs.

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

An overdose could occur if your animal eats a large amount this medication. 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. Always check the prescription label to be sure you are giving the medication correctly.

- Clean and dry the outer part of the ear if instructed by your veterinarian.
- Shake the bottle before each use.
- Apply the medicine to your animal's ear as directed by your veterinarian. Try not to touch the ear with the tip of the bottle to prevent contamination.
- Gently massage the base of the ear to help spread the medication.
- Be sure you understand how long your veterinarian wants you to use this medication.

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

If you miss a dose, give it as soon as you remember and then continue with the regular dosing schedule. If it is close to the time for the next dose, skip the missed dose, and then continue the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- At room temperature
- Out of reach of other animals and children

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, throw the bottle away in 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?

- Follow-up examinations are important for treatment of your animal's condition. Do not miss these important recheck visits.
- Long-term use of topical ear medicines with steroid anti-inflammatory agents has been associated with side effects related to hormonal excess in dogs.
- Use of this medication 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.