

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]

Orbifloxacin/Posaconazole/Mometasone Ear Drops

(or-bi-**flox**-a-sin, **poe**-sa-**kon**-a-zole, moe-**met**-a-zone)

Description:

Topical treatment for bacterial and fungal ear infections

Other Names for this Medication:

Posatex[®]

Common Dosage Forms:

Veterinary: Each gram contains orbifloxacin 10 mg, posaconazole 1 mg, mometasone furoate 1 mg in 7.5g, 15g, or 30g 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

- Labeled for use in dogs to treat itching, inflammation, and superficial bacterial and yeast infection of the ears. Not for oral use.
- Combination of antibiotic, antifungal, and steroid ingredients
- Shake well before use.
- Do not allow medication to get in your animal's eyes, mouth, or nose.
- Prevent your animal or other animals from licking or chewing at affected areas for 20-30 minutes after application.
- Discontinue use at least 2 weeks prior to allergy testing.
- Dispose of package and unused product in regular trash. Do not pour into drain.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved this topical suspension for external use in dogs to treat inflammation in the ears caused by bacterial and yeast infections. This combination product contains an antibiotic (orbifloxacin), an antifungal (posaconazole), and a steroid anti-inflammatory (mometasone). 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 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 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 didn't work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of 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's clinical signs (eg, redness, swelling, discomfort) should start to improve after that time. Your animal should begin feeling better within 1 to 2 days. The effects of this medication are moderate in duration, meaning the effects may last for a few days, although this 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 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 or hypersensitive to any of the active ingredients (orbifloxacin, posaconazole, or mometasone)
- That have tuberculosis infections of the skin
- With a confirmed or suspected ruptured ear drum
- That are receiving other medications that are potentially toxic to the ears

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

- With small body size
- With recurring ear infections
- That have kidney or liver disease
- That are sick, old, or frail
- That are receiving certain other medications
- That are pregnant, nursing, or used for breeding

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?

This medicine is typically well tolerated in dogs.

Side effects that usually are not serious include:

- Redness or discomfort at the site of application

You do not need 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:

- Infections 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
- 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?

An overdose could occur if your animal eats the topical medication, if the treatment area covers a large part of your animal's body, or if too much medicine is applied. 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. It is helpful to have the package instructions available when calling for treatment advice.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. This medication is usually applied once daily. Do not give this medication orally. It's a good idea to always check the prescription label and package instructions to be sure you are giving the medicine correctly.

- Trim hair at the application site only as necessary.
- Shake well before use.
- Apply 4 drops once daily directly into the ear canal for dogs weighing less than 30 lbs, or apply 8 drops once daily for dogs weighing more than 30 lbs.
- Avoid contact with eyes, mouth, and nose.
- Wash hands after applying.
- Do not allow animal to scratch at medicated sites, as this will delay healing and possibly introduce more infection to the area. If necessary, your veterinarian may place a collar on your animal to prevent licking and chewing of the affected area.
- These medicated products 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, skip the dose you missed and give it at the next scheduled time. Do not double-up or give extra doses.

How should I store this medication?

- Store this medication in the original container at temperatures between 35.6°F-86°F (2°C-30°C).
- 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?

- Not for use in humans. Keep this and all drugs out of reach of children. In case of accidental skin contact, wash area thoroughly with water. Avoid contact with eyes. In case of accidental ingestion by humans, contact a physician immediately. Physicians may contact a Poison Control Center for advice concerning cases of ingestion by humans.
- Humans with hypersensitivity to mometasone, fluoroquinolone antibiotics, or azole antifungals should not handle this product.
- It is recommended to wear gloves while applying this product; always wash your hands after applying this medication and all medications.

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

Do not flush the contents of these products 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, place unused medication and the packaging in a sealable plastic bag to prevent medication from leaking, and throw the bag out with the regular trash. Do not save leftover product for future use or give it to others.

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.
- Use of this medicine 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.
- Long-term use of topical ear medicines with corticosteroids has been associated with side effects related to hormonal excess in dogs.

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

Special Instructions
