

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]

Gentamicin/Miconazole/Hydrocortisone Otic Suspension

(*jen-ta-mye-sin, mye-kah-nah-zole, hye-droe-kor-ti-zone*)

Description:

Agent for treatment of bacterial and fungal ear infections

Other Names for this Medication:

EasOtic[®]

Common Dosage Forms:

Veterinary: Gentamicin sulfate 1.5 mg/mL, miconazole nitrate 15.1 mg/mL, hydrocortisone aceponate 1.11 mg/mL in a 10-mL canister.

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

- This medicine is labeled for use in dogs to treat external bacterial and yeast ear infections.
- For topical use only; not for oral use.
- Do not use this product in animals with a damaged or suspected damaged ear drum.
- Prevent your animal or other animals from licking or chewing at affected areas for 20 to 30 minutes after application.
- Do not allow medication to get in your animal's eyes, mouth, or nose.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved this topical medicine combination for use in dogs to treat bacterial and yeast ear infections. This combination product contains an antibiotic (gentamicin), an antifungal (miconazole), and a steroid anti-inflammatory (hydrocortisone). 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; however, you may not see the effects of this medication outwardly. Your animal should begin feeling better within 1 to 2 days. The effects of this medication are moderate in duration, meaning they may last for a few days, 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 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 gentamicin, miconazole, or hydrocortisone
- With a confirmed or suspected ruptured ear drum
- That are pregnant, nursing, or used for breeding

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

- With recurring ear infections
- That have kidney or liver problems

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.

Side effects that usually are not serious include:

- Redness or discomfort at the site of application

Contact your veterinarian if any of these signs are severe, worsen, or continue to be a problem.

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

- Loss of appetite, vomiting, or diarrhea
- Sudden hearing loss
- Progressive ear pain
- Head tilt or walking in circles
- Increased thirst (frequent drinking of large quantities of water) and frequent urination

Contact your veterinarian immediately if you see any of these side effects.

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 you witness or suspect an overdose, contact your veterinarian or an animal poison control center. 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. Always review the prescription label and package instructions if available.

- Shake well before each use.
- On the first use, prime the canister by depressing the pump 1-2 times to fill the tip with a full dose of product.
- Insert the tip into the affected ear canal(s) and apply a single pump (1 mL) of the suspension once daily for 5 days, or per your veterinarian's instructions.
- Avoid contact with your animal's eyes, mouth, and nose.
- Wash hands after applying.

- Do not allow animal to scratch at the ears as this may 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 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. Talk to your veterinarian before stopping this medication, 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 provided container at room temperature and protected from light.
- If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow provided storage recommendations and expiration date for the product.
- Keep away from other animals and children.

Can handling this medication be hazardous to me, my family, or other animals?

- Humans with hypersensitivity to hydrocortisone, aminoglycoside 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. In case of accidental skin contact, wash area thoroughly with water. Avoid contact with eyes.
- Not for use on humans.
- 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.

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, mix the contents 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 product for future use or give it to others to use.

What other information is important for this medication?

- Contact your veterinarian if infection does not respond to medication, does not appear to be healing, worsens, or if the ear infection recurs after treatment is complete.
- Follow-up examinations are important for treatment of your animal's condition. Do not miss these important recheck visits.
- Use this medicine only under the guidance of your veterinarian. Use of this product in your animal's ear without an examination can lead to hearing loss.
- Residual activity from steroid-containing products may affect allergy testing. Unless your veterinarian tells you otherwise, stop using steroid- or antihistamine-containing products 2 weeks before allergy testing.
- 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.

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