

Clotrimazole, Gentamicin sulfate, & Betamethasone valerate Topical Ointment

(kloe-trye-ma-zole, jen-ta-mye-sin, bay-ta-meth-a-sonē)

Description:

Topical treatment for skin and ears

Other Names for this Medication: Otomax[®]

Common Dosage Forms:

Veterinary: Clotrimazole 1%, gentamicin sulfate 0.3%, and betamethasone valerate 0.1% in 7.5 g & 15 g tubes and 15 g, 30 g, & 215 mL bottles.

Antimicrobial Classification:

Highly Important

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 of antibiotic, antifungal, and steroid ingredients allows for efficient delivery of multiple medications with each application.
- This medicine can be used to treat superficial skin and ear infections.
- Prevent your animal from licking or chewing at affected areas for 20-30 minutes after application.
- Do not allow medication to get in your animal's eyes.
- Always wash hands after applying medication, or consider wearing gloves while applying.

How is this medication useful?

Combination topical treatments contain multiple active ingredients, making it easier to treat bacterial, fungal, and inflammatory skin conditions.

- Clotrimazole, an antifungal, is used to treat ringworm (dermatophytosis) and other yeast infections of the skin.
- Gentamicin sulfate, an antibiotic, treats superficial bacterial infections of the skin.
- Betamethasone valerate, a steroid, is a cortisone-like medicine that relieves itching and inflammation.

The FDA (U.S. Food & Drug Administration) has approved this topical medicine combination for use in dogs and cats to treat infectious and inflammatory conditions of the skin, ears, and anal glands. The FDA allows veterinarians to prescribe and use human products containing these drugs in animals 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 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, herbal therapies, or other topical medicines) 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 any of the ingredients found in the combination product.
- That have tuberculosis infections of the skin.
- With a confirmed or suspected ruptured ear drum.

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

- With small body size (eg, toy breeds).
- That require treatment of large areas.
- With recurring 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 and cats, this medicine is typically well tolerated. *Side effects that usually are not serious include:*

- Redness or discomfort at the site of application.

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:

- 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.
- Development of sores around the mouth.
- Increased thirst (eg, frequent drinking of large quantities of water) and frequent urination.
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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. 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 medicine correctly.

- Trim hair at the application site only as necessary.
- This medicine is typically prescribed to apply to affected areas twice daily.
- When treating skin infections, daily to weekly baths with a medicated shampoo may also be prescribed; massage shampoo into hair coat well, and leave in contact with skin for at least 10 minutes before rinsing well with cool water. Wait for skin and hair coat to dry before applying the ointment.
- Avoid contact with eyes, mouth, and nose.
- Do not allow animal to lick or chew at affected 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 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. After that, return to the regular dosing schedule. Do not double-up or give extra doses.

How should I store this medication?

- Store this medication in the original container 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?

It is recommended to wear gloves while applying these medicated products; always wash your hands after applying the medication. **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?

- Topical combination medications may be suitable for infectious and inflammatory skin and ear conditions.
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Some skin infections may resolve completely with use of topical treatments, but others may also require oral medications.

This medicine may be absorbed across the skin and have effects throughout the body when applied to large areas or areas with open sores; small animals and patients receiving prolonged treatment may also be affected. Effects on the rest of the body can happen with any topically applied medication; however, the risk is greater with steroids.

- 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.
- Follow-up exams 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.

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