Mometamax Single™
(gentamicin, posaconazole, and mometasone furoate otic suspension)

What to expect after treatment with Mometamax Single™

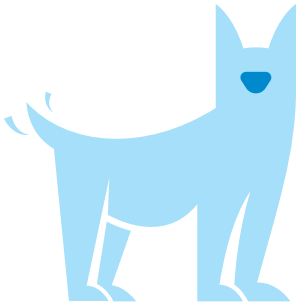
Your dog has just been treated for otitis externa—a common inflammatory condition of the outer ear canal that may also involve a possible infection. Otitis externa can be caused by many different factors.

What are the benefits of Mometamax Single?

One in-clinic dose
No need to treat at home

Rapid, long-lasting, and reliable relief
Relief lasts more than 4 weeks

Triple action
Kills bacteria and yeast and reduces redness, swelling, and pain



Work with your veterinarian to understand the cause of your dog's ear infection.

To support your dog's recovery, follow these tips:

- Avoid getting water in the ears (either through bathing or swimming) for at least 4 weeks—or until your veterinarian gives the go-ahead.
- Do not pluck hair in or near the ears.
- Do not put any medicine or ear products (including cleaners) in or near the ears.

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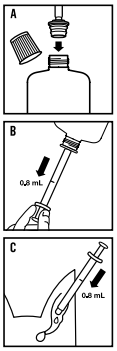
(gentamicin, posaconazole, and mometasone furoate otic suspension)

For Otic Use in Dogs Only
Do not use in cats
Antibacterial, antifungal, and anti-inflammatory
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DOSAGE AND ADMINISTRATION:
Mometamax Single should be administered by veterinary personnel. The dose volume is 0.8 mL per affected ear.
Verify the tympanic membrane is intact prior to administration (see **Contraindications, Animal Safety Warnings and Precautions**).



1. Clean and dry the external ear canal before administering the product.
2. **Shake bottle vigorously for 15 seconds.**
3. Before first use, unwrap the syringe with the attached adapter.
4. Remove the cap from the bottle and insert the syringe with the attached adapter by pressing it firmly into the top of the bottle using the attached syringe (see figure **A**).
5. Invert the bottle and draw up 0.8 mL (see figure **B**).
6. Return the bottle to an upright position and remove the syringe from the adapter. Leave the adapter in place in the bottle for all subsequent uses.
7. Replace the cap on the bottle.
8. Place the tip of the syringe at the entrance of the external ear canal and administer the 0.8 mL dose (see figure **C**). The applied dose will flow into the ear canal.
9. Gently massage the base of the ear to ensure distribution of the product throughout the ear canal.
10. **Restrain the dog post-application to minimize head shaking** and to reduce potential splatter of product and accidental eye exposure in people and dogs.
11. Use a new syringe for each affected ear. **Shake the bottle vigorously** (with the cap on the bottle to prevent leakage) **for 15 seconds before drawing up each new dose.**
12. The duration of the effect should last 33 days. Cleaning the ear after dosing may affect product effectiveness.
13. Only twenty doses can be accurately withdrawn from the bottle. Discard the bottle 3 months after opening or after 20 doses, whichever comes first.

CONTRAINDICATIONS:
Do not use in dogs with known tympanic membrane perforation (see **Animal Safety Warnings and Precautions**).
Do not use in dogs with known or suspected hypersensitivity to gentamicin, posaconazole, or mometasone furoate.

WARNINGS AND PRECAUTIONS:

USER SAFETY WARNINGS:
Not for human use. Keep this and all drugs out of the reach of children. In case of accidental ingestion by humans, contact a physician immediately.
In case of accidental skin contact, wash area thoroughly with water.
Avoid contact with eyes. If contact with the eyes occurs, flush thoroughly with water for at least 15 minutes. If wearing contact lenses, rinse eyes first then remove the contact lenses and continue to rinse. If symptoms develop, seek medical advice.
Humans with known hypersensitivity to gentamicin, posaconazole, and/or mometasone furoate should avoid handling this product.

ANIMAL SAFETY WARNINGS AND PRECAUTIONS:
For otic use in dogs only. Do not use in cats.
Restrain the dog to minimize post-application head shaking. Reducing the potential for splatter of product helps prevent accidental eye exposure in people and dogs (see **Dosage and Administration, User Safety Warnings**).
The use of Mometamax Single in dogs with perforated tympanic membranes has not been evaluated. The integrity of the tympanic membrane should be confirmed before administering the product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment.
Do not administer orally.
Use of topical otic corticosteroids has been associated with adrenocortical suppression and iatrogenic hyperadrenocorticism in dogs (see **Target Animal Safety**).
Use with caution in dogs with impaired renal function. Gentamicin, one of the active ingredients in Mometamax Single, is associated with nephrotoxicity.
The safe use of Mometamax Single in dogs used for breeding purposes, during pregnancy, or during lactation has not been evaluated.

ADVERSE REACTIONS:
The following adverse reactions were reported during the course of a U.S. field study for treatment of otitis externa in dogs treated with Mometamax Single.

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Mometamax Single (N=245)	Control (N=127)
Vomiting	21 (8.6%)	4 (3.1%)
Decreased appetite	9 (3.7%)	2 (1.6%)
Pruritus	8 (3.3%)	2 (1.6%)
Ear pruritus	7 (2.9%)	1 (0.8%)
Disorientation	3 (1.2%)	0 (0.0%)

CONTACT INFORMATION:
For technical information or to report a suspected adverse event, please contact Merck Animal Health at 1-800-224-5318 or https://www.merck-animal-health-usa.com. Safety Data Sheets (SDSs) can be found at https://www.merck.com/products/safety-data-sheets/#.
For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

EFFECTIVENESS:
In a multicenter, well-controlled, randomized, double-masked field study, Mometamax Single was evaluated against a vehicle control in 372 dogs with otitis externa. Two hundred forty-five dogs were administered Mometamax Single, and 127 dogs were administered the vehicle control. Treatment (0.8 mL) was administered once on Day 0 to the affected ear(s). Prior to treatment, the ear(s) was cleaned with saline. Dogs were evaluated on Days 0, 7, 14, and 33. Blood work and urinalysis were obtained on Day 0 pre-treatment and on Day 33 at study completion. Four clinical signs associated with otitis externa were evaluated: erythema, swelling, ulceration, and exudate. Success was based on clinical improvement on Day 33. Of the 163 dogs included in the effectiveness evaluation, 80.5% of dogs administered Mometamax Single were successfully treated, compared to 19.6% of dogs administered the vehicle control ($p<0.0001$).
No clinically relevant treatment-related findings were noted in safety parameters.

Approved by FDA under NADA # 141-600
Made in Germany.
Distributed by Intervet Inc. (d/b/a Merck Animal Health), Rahway, NJ 07065.

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The risk information provided here is not comprehensive. To learn more about Mometamax Single™ talk with your veterinarian. The FDA-approved product labeling can be found by scanning the QR code below, or by calling Technical Service at 1-800-224-5318 or Customer Service at 1-800-521-5767.

IMPORTANT SAFETY INFORMATION: Mometamax Single is for otic use in dogs only. Do not use in cats. Mometamax Single should be administered by veterinary personnel. Do not use in dogs with known tympanic membrane perforation. The integrity of the tympanic membrane should be confirmed before administering the product. Reevaluate the dog if hearing loss or signs of vestibular dysfunction are observed during treatment. Do not use in dogs with known or suspected hypersensitivity to gentamicin, posaconazole, or mometasone furoate. Avoid contact with eyes. For complete instructions and safety information, refer to the product label.

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