

Mometamax Single™

(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.

DESCRIPTION:

Each milliliter of Mometamax Single contains gentamicin sulfate, equivalent to 8.6 mg gentamicin; 2.6 mg of posaconazole; and mometasone furoate monohydrate, equivalent to 2.1 mg mometasone furoate, in a mineral oil-based system containing a plasticized hydrocarbon gel.

A 0.8 mL dose volume of Mometamax Single delivers approximately 6.88 mg gentamicin, 2.08 mg posaconazole, and 1.68 mg mometasone furoate.

INDICATIONS:

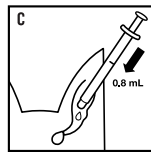
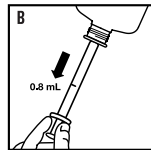
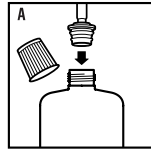
Mometamax Single is indicated for the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius* and *Pseudomonas aeruginosa*) in dogs.

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**).

- Clean and dry the external ear canal before administering the product.
- Shake bottle vigorously for 15 seconds.**
- Before first use, unwrap the syringe with the attached adapter.
- 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).
- Invert the bottle and draw up 0.8 mL (see figure B).
- 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.
- Replace the cap on the bottle.
- 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.
- Gently massage the base of the ear to ensure distribution of the product throughout the ear canal.
- Restrain the dog post-application to minimize head shaking** and to reduce potential splatter of product and accidental eye exposure in people and dogs.
- 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.**
- The duration of the effect should last 33 days. Cleaning the ear after dosing may affect product effectiveness.
- 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.

CLINICAL PHARMACOLOGY:

Mometamax Single is a combination of three active ingredients: gentamicin (antibacterial), posaconazole (antifungal), and mometasone furoate (steroidal anti-inflammatory). Gentamicin is an aminoglycoside bactericidal antibiotic which acts by binding to the 30S ribosomal subunit leading to inhibition of bacterial protein synthesis. Posaconazole is a triazole antifungal which selectively inhibits an enzyme involved in the biosynthesis of ergosterol. Mometasone furoate is a corticosteroid that binds to glucocorticoid receptors resulting in anti-inflammatory activity.

MICROBIOLOGY:

The compatibility and additive effect of each of the components in Mometamax Single was demonstrated in an *in vitro* non-interference study which utilized organisms collected from clinical cases of otitis externa in dogs. It determined that gentamicin and posaconazole inhibit the growth of bacteria and yeast commonly associated with otitis externa in dogs. No synergistic or antagonistic effect of the two antimicrobials was demonstrated. The addition of mometasone furoate to the combination did not impair antimicrobial activity.

In a field effectiveness study, each target microbial species (*S. pseudintermedius*, *P. aeruginosa*, and *M. pachydermatis*) was successfully treated in at least 10 or more dogs receiving Mometamax Single (see **Effectiveness**).

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.

TARGET ANIMAL SAFETY:

Margin of Safety Study: Mometamax Single was administered to 11- to 12-week-old puppies (4 dogs/sex/group) with 1X, 3X, or 5X the labeled dose of 0.8 mL/ear to both ears once every two weeks for a total of 3 doses on Days 1, 15, and 29. The control group received vehicle control on the same dosing schedule. No treatment-related effects on food consumption, body weights, clinical observations, physical examinations, otoscopic examinations, hearing assessments, electrocardiography, ophthalmic examinations, coagulation parameters, serum chemistry, urinalysis, fecal evaluations, or gross pathology were observed. Mometamax Single administration was associated with mild eosinopenia in the 3X and 5X groups and suppression of serum cortisol levels in the 1X, 3X, and 5X groups. On Day 30, two of eight 1X dogs and all 3X and 5X dogs had suppressed baseline cortisol levels. All control and 1X dogs had normal post-ACTH stimulation cortisol response levels. Seven of eight dogs in each of the 3X and 5X groups had suppressed ACTH stimulation responses but remained within the normal reference range. The low baseline and post-ACTH test cortisol levels correlated with the pathology results of lower mean adrenal weights and mild atrophy of the adrenal cortex in the 3X and 5X groups. Histopathology demonstrated mild atrophy of the external auditory canal epidermis and mild atrophy of the external surface of the tympanic membrane in the 1X, 3X, and 5X groups. One male in the 3X group and one male in the 5X group had a minimal epidermal erosion/ulcer in the external auditory canal of one ear, whereas this finding was not noted in the control or 1X treatment groups.

STORAGE CONDITIONS:

Store at temperatures between 2°-30°C (36°-86°F). Discard 3 months after opening or after 20 doses, whichever comes first.

HOW SUPPLIED:

Mometamax Single (gentamicin, posaconazole, and mometasone furoate otic suspension) is supplied in a bottle containing 24 mL (20 doses) co-packaged with one plastic-wrapped dosing syringe with attached bottle adapter, and 19 additional dosing syringes.

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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