

Approval Date: JAN 9 2003

FREEDOM OF INFORMATION SUMMARY

NADA 141-177

MOMETAMAX™ Otic Suspension for Dogs

(gentamicin sulfate, mometasone furoate monohydrate, clotrimazole)

For the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas spp.* [including *P. aeruginosa*], coagulase positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis* and beta hemolytic streptococci)

Sponsored by:

SCHERING-PLOUGH ANIMAL HEALTH

NADA 141-177

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FREEDOM OF INFORMATION SUMMARY

1. BACKGROUND INFORMATION:

- a. *File Number:* NADA 141-177
- b. *Sponsor:* Schering-Plough Animal Health Corporation
1095 Morris Avenue
Union, NJ 07083
Drug Labeler Code: 000061
- c. *Established Name:* Gentamicin sulfate, USP; mometasone furoate monohydrate; and clotrimazole, USP suspension
- d. *Proprietary Name:* Mometamax™ Otic Suspension
- e. *Dosage Form:* Otic Suspension
- f. *How Supplied:* 15g, 30g, and 215g plastic bottles
- g. *How Dispensed:* Rx
- h. *Amount of Active Ingredients:* Each gram contains 3-mg gentamicin, 1-mg mometasone, and 10-mg clotrimazole.
- i. *Route of Administration:* Otic
- j. *Species/Class:* Dogs
- k. *Recommended Dosage:* For dogs weighing less than 30 lbs, instill 4 drops from the 15-g and 30-g bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lbs or more, instill 8 drops from the 15- or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once daily for 7 days.
- l. *Pharmacological Category:* Gentamicin - aminoglycoside antibiotic
Mometasone - synthetic adrenocorticoid
Clotrimazole - imidazole antifungal agent

m. *Indications:*

MOMETAMAX™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas spp.* [including *P. aeruginosa*], coagulase positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis* and beta hemolytic streptococci).

n. *Effect of Supplement:*

This supplemental approval adds the additional dosing frequency of once daily administration.

II. EFFECTIVENESS:

A. Dosage Characterization:

An original new animal drug application for Mometamax™ Otic Suspension for Dogs (NADA 141-177) was approved on December 5, 2000. The studies demonstrating the effectiveness of Mometamax™ administered twice daily are summarized in the original NADA 141-177 Freedom of Information Summary. This NADA 141-177 supplement is supported by data from one field study to confirm the effectiveness of Mometamax™ administered once daily for 7 days

B. Field Study:

A Negatively Controlled Study to Assess the Field Effectiveness and Safety of Mometamax (SCH 480) Otic Suspension administered once daily (Study C00-055-00).

Investigators:

The following investigators produced a sufficient number of cases to be included in the effectiveness analysis:

Dr. Greg Tremoglie Glenmoore Veterinary Hospital 3 Andover Rd. Glenmoore, PA 19343	Dr. Charles Schwirck Hillsborough Veterinary Hospital 210 Route 206 South Somerville, NJ 08876
Dr. Dave Lukof Harleysville Veterinary Hospital 391 Main St. Harleysville, PA 19438	Dr. Roger Sifferman Bradford Park Veterinary Hospital 1255 East Independence Springfield, MO 65804

Dr. Karen Oberhansley Whitehouse Veterinary Hospital P. O. Box 293 358 Main St. Whitehouse Station, NJ 08889	Dr. Dean J. Rund Grant Avenue Pet Hospital 1037 S. Grant Avenue Springfield, MO 65807
Dr. Robert Yelland VCA Lewelling Veterinary Clinic 525 Lewelling Boulevard San Leandro, CA 94579	Dr. Richard Benjamin Berkeley Dog & Cat Hospital 2126 Haste Street Berkeley, CA 94704

General Design of the Investigation:

Purpose: To compare the safety and effectiveness of a clotrimazole-gentamicin-mometasone (Mometamax™) combination otic product, administered once daily, to that of an excipient negative control, administered once daily, under clinical conditions of use against concurrent bacterial and yeast (*Malassezia pachydermatis*) infections.

Species: Canine, multiple breeds

Number of Subjects: 47 treated with Mometamax™ and 48 treated with excipient base (mineral oil in a plasticized hydrocarbon gel) were included for assessment of safety. Of these cases, 39 dogs treated with Mometamax™ and 36 treated with excipient base were included in the evaluation for effectiveness.

Age Range: 5 months -16 years

Weight Range: 5 lbs.-168 lbs.

Sex: 28 females and 19 males were treated with Mometamax™ and 24 females and 24 males were treated with excipient base.

Test Articles:

Mometamax™ Otic Suspension: 10 mg/g clotrimazole, 1.0 mg/g mometasone furoate monohydrate, and 3.0 mg/g gentamicin sulfate.

Negative Control: same excipient base found in Mometamax™, mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage Groups:

Mometamax™ Otic Suspension

Negative Control (Excipient base)

Dosage: < 30 lbs - 4 drops per affected ear or
≥ 30 lbs - 8 drops per affected ear

Route of Administration: Otic

Frequency of Treatment: Once a day for 7 days.

Duration of Study: Animals were treated for 7 days with either Mometamax™ or excipient base and returned for reevaluation 2 - 7 days after treatment was completed.

Inclusion Criteria: Dogs had concurrent bacterial and *Malassezia pachydermatis* infections in either one ear or both ears as determined by an ear swab. The otitis externa was of sufficient severity that the sum of the clinical scores (graded on a scale of 0-3) associated with discomfort, ear canal erythema, ear canal swelling and exudate quantity was greater than or equal to 5. If both ears were infected, only the right ear was evaluated. Dogs had none of the exclusion criteria present, including otic foreign bodies, concurrent medications that could confound the study (i.e. otic preparations, systemic corticosteroids, antibiotic or antifungal therapy), occlusive masses, ruptured tympanic membranes, staff-owned pet, or pets enrolled in other field studies.

Parameters measured: A complete physical (including a hearing [clap] test) and otoscopic examination was performed on both ears. The ears were cleaned with an ear cleansing solution free of antimicrobial and anti-inflammatory activity. Discomfort, ear canal erythema, and ear canal swelling were considered the primary variables. Secondary variables included: odor, pinna erythema, exudate type, exudate quantity, and investigator and owner evaluations. All variables were evaluated prior to treatment and 2-7 days after completion of treatment.

Primary Effectiveness Variables:

- Discomfort (none, mild, moderate, marked)
- Ear canal erythema (none/normal, mild, moderate, marked)
- Ear canal swelling (none/normal, mild, moderate, marked)

Results:

Discomfort:

Upon final evaluation of discomfort: 74% (29/39) and 58% (21/36) of the dogs in Mometamax™ and placebo control groups, respectively, showed none to mild discomfort.

Ear Canal Erythema:

Upon final evaluation of ear canal erythema: 80% (31/39) and 50% (18/36) of the dogs in Mometamax™ and placebo control groups, respectively, showed none to mild ear canal erythema.

Ear Canal Swelling:

Upon final evaluation of ear canal swelling: 82% (32/39) and 67% (26/36) of the dogs in Mometamax™ and placebo control groups, respectively, showed none to mild ear canal swelling.

Statistical Analysis:

For discomfort, canal erythema, canal swelling, pinna erythema, exudate odor and quantity of exudate, the animals that showed improvement from Day 0 to Day 8 in the clinical score were classified as “improved.” If the animals stayed the same or got worse, they were classified as “Stayed the same / Got worse.” Any animal that was normal at both the start and end of the study for a certain variable was excluded from the analysis for that variable.

The primary variables, discomfort, canal erythema and canal swelling, were analyzed with an exact Mantel Haenszel analysis of 2x2 tables, stratified by site, to compare the percentage of animals showing improvement with Mometamax compared with the placebo.

The secondary variables were pooled across sites and analyzed with an exact test of the difference between two percentages. The percentage of improvement was analyzed for the variables pinna erythema, exudate odor, and quantity of exudate. For owner evaluation and investigator evaluation, the percentage of cases that were rated as either “excellent” or “good” was analyzed. For type of exudate, animals that had purulent exudate on day 0 and either none, waxy or serous exudate on day 8 were classified as “improved.” Animals that had purulent exudate on day 8 were classified as “not improved.” Animals that had either none, waxy or serous type of exudate on day 0 and either none, waxy or serous type of exudate on day 8 were excluded from the calculation of percent improvement.

Statistical significance was declared at $p \leq 0.05$. See Table 1 for the results.

Table 1 Improvement in Clinical Variables

	Mometamax	Placebo	p-value, Mometamax vs. Placebo
Primary clinical variables			
Discomfort	70.3% (n=37) ^a	41.7% (n=36)	p=0.0326
Canal Erythema	74.4% (n=39)	36.1% (n=36)	p=0.0016
Canal Swelling	71.4% (n=35)	48.5% (n=33)	p=0.0436
Secondary clinical variables			
Pinna Erythema	73.5% (n=34)	50.0% (n=34)	p=0.0701
Type of Exudate ^b	57.1% (n=7)	40.0% (n=5)	p=0.6595
Quantity of Exudate	61.5% (n=39)	52.8% (n=36)	p=0.4821
Odor of Exudate	72.2% (n=36)	21.9% (n=32)	p=0.0020
Investigator Evaluation ^c	61.5% (n=39)	19.4% (n=36)	p=0.0022
Owner Evaluation ^c	74.4% (n=39)	55.6% (n=36)	p=0.1108

^a The number of animals in this group on which the percentage is based. The animals that were normal on both Day 0 and Day 8 were excluded.

^b Animals that had either none, waxy or serous type of exudate on Day 0 and either none, waxy or serous type of exudate on Day 8 were excluded.

^c Percent of animals that are either "Excellent" or "Good."

Adverse Reactions:

There were no adverse reactions reported during the study in either of the Mometamax™ or placebo control groups.

Conclusion:

This controlled field study demonstrated that Mometamax™, a combination otic product, administered once daily to dogs as recommended was both safe and effective for the treatment of otitis externa in dogs.

III. ANIMAL SAFETY:

Target Animal Safety information for Mometamax™ Otic Suspension is incorporated by reference to the original new animal drug application (NADA 141-177), which was approved on December 5, 2000.

In a field study not used to support effectiveness due to problems with the study design, ataxia, proprioceptive deficits, and increased water consumption were observed in less than 1% of 117 dogs following once-daily treatment with Mometamax™ Otic Suspension. Treatment with the investigational drug could not be ruled out as contributing to these observations. The ataxia and proprioceptive deficits reported in one dog resulted in that dog's withdrawal from the study.

IV. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Keep this and all drugs out of the reach of children."

V. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that Mometamax™ Otic Suspension, when used under labeled conditions of use, is safe and effective.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise and proper diagnosis are required to determine the presence

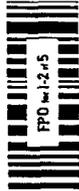
of otitis externa and the presence of bacterial and/or yeast and to monitor the safe use of the product.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the Mometamax™ once daily application for which this supplement is approved.

Schering Plough holds the following patents on mometasone: 5,502,222 (expires June 1, 2014), 5,616,742 (expires May 22, 2015), 5,750,745 (expires May 30, 2015), 5,886,200 (expires June 25, 2017), and 6,127,353 (expires October 3, 2017).

VI. LABELING (Attached):

- A. Package Insert
- B. Bottle Label (15g, 30g, 215g)
- C. Carton Label (15g, 30g, 215g)



F-00000000
NADA #141-177. Approved by FDA.

MOMETAMAX™
(GENTAMICIN SULFATE, USP;
MOMETASONE FUROATE
MONOHYDRATE;
AND CLOTRIMAZOLE, USP,
OTIC SUSPENSION)

VETERINARY
For Otic Use in Dogs Only

CAUTION Federal law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

DESCRIPTION Each gram of MOMETAMAX Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel

PHARMACOLOGY

Gentamicin: Gentamicin sulfate is an aminoglycoside antibiotic active against a wide variety of gram-negative and gram-positive bacteria. *In vitro* tests have determined that gentamicin is bactericidal and acts by inhibiting normal protein synthesis in susceptible microorganisms. In clinical trials, gentamicin was shown to have a range of activity against the following organisms commonly isolated from infected canine ears: *Pseudomonas* spp. (including *P. aeruginosa*), coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis* and beta-hemolytic streptococci.

Mometasone: Mometasone furoate monohydrate is a synthetic adrenocorticoid characterized by a novel (2') furoate 17-ester having chlorine at the 9 and 21 positions, which have shown to possess high topical potency.

Systemic absorption of mometasone furoate ointment was found to be minimal (2%) over 1 week when applied topically to dogs with intact skin. In a 6-month dermal toxicity study using 0.1% mometasone ointment on healthy intact skin in dogs, systemic effects typical of corticosteroid therapy were noted.

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the integrity of the epidermal barrier. Topical corticosteroids can be absorbed from normal, intact skin. Inflammation can increase percutaneous absorption. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways

PRODUCT INFORMATION

similar to systemically administered corticosteroids.

Clotrimazole: Clotrimazole is a broad-spectrum antifungal agent that is used for the treatment of dermal infections caused by various species of dermatophytes and yeast. The primary action of clotrimazole is against dividing and growing organisms.

In vitro, clotrimazole exhibits fungistatic and fungicidal activity against isolates of *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis*, *Candida* spp., and *Malassezia pachydermatis*. Resistance to clotrimazole is very rare among the fungi that cause superficial mycoses. In an induced otitis externa study using dogs infected with *Malassezia pachydermatis*, 1% clotrimazole in the vehicle formulation was effective both microbiologically and clinically in terms of reduction of exudate, odor, and swelling.

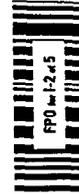
In studies of the mechanism of action, the minimum fungicidal concentration of clotrimazole caused leakage of intracellular phosphorus compounds into the ambient medium with concomitant breakdown of cellular nucleic acids and accelerated potassium efflux. These events began rapidly and extensively after addition of the drug. Clotrimazole is very poorly absorbed following dermal application.

Gentamicin-Mometasone-Clotrimazole: By virtue of its three active ingredients, MOMETAMAX Otic Suspension has antibacterial, anti-inflammatory, and antifungal activity. In clinical field trials, MOMETAMAX Otic Suspension was effective in the treatment of otitis externa associated with bacteria and *Malassezia pachydermatis*. MOMETAMAX Otic Suspension reduced discomfort, redness, swelling, exudate, and odor.

INDICATIONS MOMETAMAX Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

CONTRAINDICATIONS If hypersensitivity to any of the components occurs, treatment should be discontinued and appropriate therapy instituted. Concomitant use of drugs known to induce ototoxicity should be avoided. Do not use in dogs with known perforation of eardrums.

WARNINGS The use of these components has been associated with deafness or partial hearing loss in a small number of sensitive dogs (eg geriatric). The hearing deficit is usually temporary. If hearing or vestibular dysfunction is noted during the course of treatment, discontinue use



of MOMETAMAX™ Otic Suspension immediately and flush the ear canal thoroughly with a non-ototoxic solution.

Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs that received corticosteroids during pregnancy.

Field and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

PRECAUTIONS Before instilling any medication into the ear, examine the external ear canal thoroughly to be certain the tympanic membrane is not ruptured in order to avoid the possibility of transmitting infection to the middle ear as well as damaging the cochlea or vestibular apparatus from prolonged contact.

Administration of recommended doses of MOMETAMAX Otic Suspension beyond 7 days may result in delayed wound healing.

If overgrowth of nonsusceptible bacteria or fungi occurs, treatment should be discontinued and appropriate therapy instituted.

Avoid ingestion. Adverse systemic reactions have been observed following the oral ingestion of some topical corticosteroid preparations. Patients should be closely observed for the usual signs of adrenocorticoid overdosage which include sodium retention, potassium loss, fluid retention, weight gain, polydipsia, and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects.

Use of corticosteroids, depending on dose, duration, and specific steroid, may result in endogenous steroid production inhibition following drug withdrawal. In patients presently receiving or recently withdrawn from corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in especially stressful situations.

TOXICOLOGY Field and safety studies with MOMETAMAX Otic Suspension have shown a wide safety margin at the recommended dose level in dogs (see **PRECAUTIONS/ADVERSE REACTIONS**).

ADVERSE REACTIONS

Gentamicin: While aminoglycosides are absorbed poorly from skin, intoxication may occur when aminoglycosides are applied topically for prolonged periods of time to large wounds, burns, or any denuded skin, particularly if there is renal insufficiency. All aminoglycosides have the potential to produce reversible and irre-

versible vestibular, cochlear, and renal toxicity.

Mometasone: ALP (SAP) and ALT (SGPT) enzyme elevations, weight loss, anorexia, polydipsia, polyuria, neutrophilia, and lymphopenia have occurred following the use of parenteral, high-dose and/or prolonged or systemic synthetic corticosteroids in dogs. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Clotrimazole: The following have been reported occasionally in humans in connection with the use of clotrimazole: erythema, stinging, blistering, peeling, edema, pruritus, urticaria, and general irritation of the skin not present before therapy.

MOMETAMAX Otic Suspension: In field studies following once-daily treatment with MOMETAMAX Otic Suspension, ataxia, proprioceptive deficits, and increased water consumption were observed in less than 1% of 164 dogs. In a field study following twice-daily treatment with MOMETAMAX Otic Suspension, inflammation of the pinna and diarrhea were observed in less than 1% of 141 dogs.

DOSE AND ADMINISTRATION

The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the 15 g and 30 g bottles (2 drops from the 215 g bottle) of MOMETAMAX Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the 15 g and 30 g bottles (4 drops from the 215 g bottle) once daily into the ear canal. Therapy should continue for 7 consecutive days.

HOW SUPPLIED MOMETAMAX Otic Suspension is available in 15 g (NDC 0061-1246-04), 30 g (NDC 0061-1246-01), and 215 g (NDC 0061-1246-02) plastic bottles.

Store between 2° and 25°C (36° and 77°F).
Shake well before use.

Schering-Plough Animal Health Corp.,
Union, NJ 07083

U.S. Patent Nos. 5,502,222; 5,616,742;
5,750,745; 5,886,200; 6,127,353; 6,180,781

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Rev. 0/00 B-00000000
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ENLARGED FOR EASIER REVIEW

NDC 0061-1246-04

15 g

Mometamax™
(GENTAMICIN SULFATE, USP;
MOMETASONE FUROATE MONO-
HYDRATE, AND CLOTRIMAZOLE,
USP, OTIC SUSPENSION)

Keep Out of Reach of Children.

Caution: Federal law restricts this drug to use
by or on the order of a licensed veterinarian.

NADA #141-177, Approved by FDA.



Schering-Plough Animal Health

LOT EXP

For otic use in dogs only

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. (including *P. aeruginosa*), coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis* and beta-hemolytic streptococci).

Each gram contains: gentamicin sulfate, USP equivalent to 5 mg gentamicin base; mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops of MOMETAMAX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops once daily into the ear canal. Therapy should continue for 7 consecutive days.

Store between 2° and 25°C (36° and 77°F). Shake well before use. U.S. Patent Nos. 5,502,222; 5,616,742; 5,750,745; 5,896,206; 6,127,823; 6,180,781

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NDC 0061 1246 01

30 g

Mometamax™
(GENTAMICIN SULFATE, USP,
MOMETASON FURATE MONO-
HYDRATE, AND CLOTRIMAZOLE,
USP, OTIC SUSPENSION)

Keep Out of Reach of Children
Caution: Federal law restricts this drug to use
by or on the order of a licensed veterinarian
NADA #141 177 Approved by FDA
Schering-Plough Animal Health



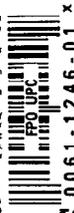
LOT EXP

For use in dogs only.
Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment
of otitis externa in dogs caused by sensitive strains of yeast (*Malassezia*
 pachydermatis) and bacteria (*Pseudomonas* spp. (including *P. aeruginosa*),
coagulase positive staphylococci, *Enterococcus faecalis*, *Franseria mirabilis*
and beta hemolytic streptococci).

Each gram contains gentamicin sulfate (USP equivalent to 3 mg gentamicin
base), mometasone furate monohydrate equivalent to 1 mg mometasone
and 10 mg clotrimazole (USP) in a mineral oil based system containing a
phosphate-hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly
cleaned and dried before treatment. Verify that the ear drum is intact. For
dogs weighing less than 30 lbs, instill 4 drops of MOMETAMAX™ Otic
Suspension once daily into the ear canal. For dogs weighing 30 lbs or more,
instill 8 drops once daily into the ear canal. Therapy should continue for
1 consecutive day.

Store between 2° and 25°C (36° and 77°F). Shake well before use.
U.S. Patent Nos. 5,562,229; 5,616,742; 5,198,745; 5,065,700; 6,177,253; 6,188,781
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NJ 07033. All rights reserved. 01-40841 000000 0000



PANTONE COLORS

MAROON 201

BLACK

NDC 0061-1246-02

215 g

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE;
AND CLOTRIMAZOLE, USP
OTIC SUSPENSION)

Keep Out of Reach of Children

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Each gram contains: gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 2 drops of MOMETAMAX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 4 drops once daily into the ear canal. Therapy should continue for 7 consecutive days.

Store between 2° and 25°C (36° and 77°F). Shake well before use.

U.S. Patent Nos. 5,502,222; 5,616,742; 5,750,745;
5,886,200; 6,127,353; 6,180,781

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81-469541

AX3 & LOT

CODE AREA

HOLDING LINES
DO NOT PRINT

PANTONE COLORS

BLACK

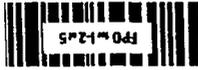


PMS 201



PMS 428





Mometamax™
(GENTAMICIN SULFATE, USP,
MOMETASONE FUROATE
MONOHYDRATE, AND CLOTRIMAZOLE,
USP OTIC SUSPENSION)

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

Description: Each gram of MOMETAMAX™ Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the bottle of MOMETAMAX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle once daily into the ear canal. Therapy should continue for 7 consecutive days.

Read accompanying directions carefully.

Store between 2° and 25°C (36° and 77°F).

Shake well before use.

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE,
AND CLOTRIMAZOLE, USP
OTIC SUSPENSION)

**For otic use
in dogs only.**

U.S. Patent Nos. 5,502,222;
5,616,742; 5,750,745; 5,896,200;
6,127,353; 6,180,781

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00000000 Rev. 0700
81-180041

NOC 0061-1246-04

15g

Mometamax™
(GENTAMICIN SULFATE, USP;
MOMETASONE FUROATE
MONOHYDRATE; AND
CLOTRIMAZOLE, USP OTIC
SUSPENSION)

**Keep Out of Reach
of Children.**

Caution: Federal law
restricts this drug to use
by or on the order of a
licensed veterinarian.

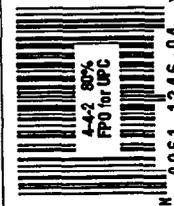
NADA #141-177, Approved by FDA.



Schering-Plough
Animal Health

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE,
AND CLOTRIMAZOLE, USP
OTIC SUSPENSION)

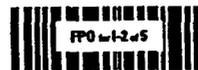
**For otic use
in dogs only.**



Mometamax™
(GENTAMICIN SULFATE, USP; MOMETASONE FUROATE MONO-
HYDRATE, AND CLOTRIMAZOLE, USP OTIC SUSPENSION)

LOT & EXP

**NO VARNISH
CODE AREA**



DIE3870



Mometamax™
(GENTAMICIN SULFATE, USP,
MOMETASONE FUROATE,
MONOHYDRATE, AND CLOTRIMAZOLE,
USP OTIC SUSPENSION)

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp (including *P. aeruginosa*), coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci)

Description: Each gram of MOMETAMAX™ Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the bottle of MOMETAMAX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle once daily into the ear canal. Therapy should continue for 7 consecutive days

Read accompanying directions carefully.

Store between 2° and 25°C (36° and 77°F).

Shake well before use.

Mometamax™
(GENTAMICIN SULFATE,
USP, MOMETASONE
FUROATE MONOHYDRATE,
AND CLOTRIMAZOLE, USP
OTIC SUSPENSION)

**For otic use
in dogs only.**

U.S. Patent Nos. 5,502,222,
5,616,742, 5,750,745, 5,886,200,
6,127,353, 6,180,781

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NDC 0061-1246-01

30 g

Mometamax™
(GENTAMICIN SULFATE, USP;
MOMETASONE FUROATE
MONOHYDRATE; AND
CLOTRIMAZOLE, USP OTIC
SUSPENSION)

**Keep Out of Reach
of Children.**

Caution: Federal law
restricts this drug to use
by or on the order of a
licensed veterinarian

NADA #141-177, Approved by FDA



Schering-Plough
Animal Health

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE,
AND CLOTRIMAZOLE, USP
OTIC SUSPENSION)

**For otic use
in dogs only.**



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Mometamax™
(GENTAMICIN SULFATE, USP; MOMETASONE FUROATE MONOHYDRATE, AND CLOTRIMAZOLE, USP OTIC SUSPENSION)

LOT & EXP

**NO VARNISH
CODE AREA**



FPO 1-2-5

DIE3970

PANTONE COLORS

BLACK



PMS 201



REDUCED



Mometamax™
(GENTAMICIN SULFATE, USP,
MOMETASONE FUROATE
MONOHYDRATE AND CLOTRIMAZOLE
USP OTC SUSPENSION)
For otic use in dogs only.

215 g

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of otitis externa in dogs caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. including *P. aeruginosa*, coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci)

Description: Each gram of MOMETAMAX™ Otic Suspension contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone; and 10 mg clotrimazole, USP in a mineral oil-based system containing a plasticized hydrocarbon gel.

Dosage and Administration: The external ear canal should be thoroughly cleaned and dried before treatment. Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 2 drops from the 215 g bottle of MOMETAMAX™ Otic Suspension once daily into the ear canal. For dogs weighing 30 lbs or more, instill 4 drops from the 215 g bottle once daily into the ear canal. Therapy should continue for 7 consecutive days.

Read accompanying directions carefully.

Store between 2° and 25°C (36° and 77°F).

Shake well before use.

U.S. Patent Nos. 5,502,222; 5,616,742; 5,750,745; 5,886,200; 6,127,253; 6,180,781

Schering-Plough Animal Health Corp.,
Kenilworth, NJ 07033

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81-180141



4-4-2 100%
FPO for UPC
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Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE;
AND CLOTRIMAZOLE,
USP OTC SUSPENSION)

For otic use in dogs only.

NDC 0061-1246-02

215 g

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE;
AND CLOTRIMAZOLE,
USP OTC SUSPENSION)

Keep Out of Reach
of Children.

Caution: Federal law
restricts this drug to use
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NADA 7141-177
Approved by FDA



Schering-Plough
Animal Health

215 g

Mometamax™
(GENTAMICIN SULFATE,
USP; MOMETASONE
FUROATE MONOHYDRATE;
AND CLOTRIMAZOLE,
USP OTC SUSPENSION)

For otic use in dogs only.