

DEC 5 2000

FREEDOM OF INFORMATION SUMMARY

NADA 141-177

MOMETAMAX™ Otic Suspension for Dogs

(gentamicin sulfate, mometasone furoate monohydrate, clotrimazole)

For use in the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

Sponsored by:

SCHERING-PLOUGH ANIMAL HEALTH

NADA - 141-177

FOSI-1

Table of Contents

I.	GENERAL INFORMATION.....	1
II.	INDICATIONS FOR USE:.....	1
III.	DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE:	1
IV.	EFFECTIVENESS:.....	2
A.	DOSE SELECTION/RATIONALE:	2
B.	FIELD INVESTIGATIONS:	3
	<i>"Comparison of Two Otic Formulations in Dogs: Otomax® Ointment vs. Gentamicin- Mometasone-Clotrimazole (SCH 480) Ointment" (Study V95-271)</i>	3
V.	ANIMAL SAFETY:	8
A.	SIX-MONTH DERMAL TOXICITY STUDY OF SCH 32088 (MOMETASONE FUROATE OINTMENT) 1% IN DOGS WITH INTACT SKIN:	8
VI.	HUMAN SAFETY:.....	11
VII.	AGENCY CONCLUSIONS:	11
VIII.	LABELING (ATTACHED):	12

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 141-177

Sponsor: Schering-Plough Animal Health Corporation
1095 Morris Ave.
Union, N. J. 07083

Established Name: Gentamicin sulfate, Clotrimazole, Mometasone furoate monohydrate

Trade Name: Mometamax™ Otic Suspension

Marketing Status: This is a prescription product that includes the caution statement as follows: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

II. INDICATIONS FOR USE:

Mometamax™ Otic Suspension is indicated for the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE:

A. Dosage Form:

Mometamax™ is a white, opaque otic suspension. The final dosage form consists of 0.3% Gentamicin Sulfate, 0.1% Mometasone furoate monohydrate, 1.0% Clotrimazole, Plasticized Hydrocarbon Gel Base and Mineral Oil USP. It is available in 15g, 30g, and 215g plastic dispensing bottles, each with attachable applicator tip for otic use.

B. Route of Administration:

Mometamax™ should be administered aurally. The external ear canal should be thoroughly cleaned and dried before treatment.

C. Approved Dose:

Verify that the eardrum is intact. For dogs weighing less than 30 lbs, instill 4 drops from the 15g or 30g bottle (2 drops from the 215g bottle) of MOMETAMAX™ Otic Suspension twice daily into the ear canal. For dogs weighing 30 lbs. or more, instill 8 drops from the 15g or 30 g bottle (4 drops from the 215g bottle) twice daily into the ear canal. Therapy should continue for 7 consecutive days.

IV. **EFFECTIVENESS:**

A. ***Dose Selection/Rationale:***

The rationale for development of this product was to provide the veterinary practitioner with a broader range of otic products while offering a new otic which combines effectiveness against otitis externa with an alternate anti-inflammatory component. Mometamax™ is identical to the currently approved Schering-Plough product, Otomax® Ointment (NADA 140-896), with the exception of the substitution of 1 mg/g mometasone furoate monohydrate (in Mometamax™) for 1 mg/g betamethasone valerate (in Otomax®). The antifungal and antibacterial data used to support the effectiveness of Otomax® were applied to Mometamax™ since the active ingredients against fungi and bacteria are unchanged. Because the only change was the one-to-one substitution of the anti-inflammatory agents, the dose selected for clinical trials for Mometamax™ was the same as for Otomax®.

In the screening that led to the identification and selection of mometasone furoate monohydrate, it was found that furoates, especially in the 17 position, exhibit high topical potency with little systemic effect. The percutaneous absorption and excretion of mometasone ointment at 1 mg/g was evaluated after single topical applications of radiolabelled ointment to rats, rabbits and dogs with intact skin. In all three species, systemic absorption was found to be minimal and ranged from 2% in dogs to 6% in rabbits over a 5-7 day period. Mometasone furoate at a concentration of 1 mg/g is currently available as the human product, Elocon® Cream.

B. Field Investigations:

"Comparison of Two Otic Formulations in Dogs: Otomax® Ointment vs. Gentamicin-Mometasone-Clotrimazole (SCH 480) Ointment" (Study V95-271)

1 Investigators:

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

Dr. R. W. Cannon Small Animal Hospital 4314 Main Street Kansas City, MO 64111	Dr. Donald Copeland Bellaire Richmond Pet Hospital 5808 Bissonnet Houston, TX 77081-6599
Dr. L. D. Eckermann Westbury Animal Hospital 4917 South Willow Drive Houston, TX 77035	Dr. Ben Garrett 1846 South Oates Dothan, AL 36301
Dr. Richard W. Green Capitol Plaza Veterinary Clinic 2200 East South Boulevard Montgomery, AL 36116	Dr. Terry Grieshaber Animal Allergy & Skin Disease Center 6327 North Keystone Indianapolis, IN 46220
Dr. K. Scott Griffin Carriage Hills Animal Clinic 3200 Eastern Bypass Montgomery, AL 36116	Dr. Andrew Pickering Wabash Valley animal Hospital 3004 South 7 th Street Terre Haute, IN 47802
Dr. Tod Schadler 2685 South High Street Columbus, OH 43207	Dr. Roger Sifferman Bradford Park Veterinary Hospital 1255 East Independence Springfield, MO 65804
Dr. Jack W. Whitmore Stuebner Airline/Champions Veterinary Hospital 16116 Stuebner Airline Spring, TX 77379	Dr. Ken D. Winters 7280 W. 105 th Street Overland Park, KS 66212 3910 W. 95 th Street Prairie Village, KS 66207
Dr. Robert Yelland Lewelling Veterinary Clinic 525 Lewelling Boulevard San Leandro, CA 94579	

2. General Design of the Investigation:

Purpose:

To compare the safety and effectiveness of a clotrimazole-gentamicin mometasone (Mometamax™) combination otic product with a FDA-approved product with similar claims (Otomax®), under clinical conditions of use against concurrent bacterial and yeast (*Malassezia pachydermatis*) infections.

Test Animals:

Species: Canine, multiple breeds

Number of Subjects: 141 treated with Mometamax™ and 146 treated with the control drug, Otomax® were evaluated for safety. Of these cases, 117 dogs treated with Mometamax™ and 123 dogs treated with Otomax® were included in the evaluation for effectiveness.

Age Range: 2 months -16.4 years

Weight Range: 5 lbs.-138.0 lbs.

Sex: 79 females and 68 males were treated with Mometamax™ and 77 females and 73 males were treated with Otomax®.

Test Articles:

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

CONTROL: Otomax® Ointment: 10 mg/g clotrimazole, 1.0 mg/g betamethasone valerate, and 3.0 mg/g gentamicin sulfate.

Treatment Schedule

Dosage Groups: Group T1 and T3 – Otomax®
Group T2 and T4 – Mometamax™

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

Route of Administration: Otic

Frequency of Treatment: Twice a day for 7 days.

Duration of Study: Animals were treated for 7 days with either Otomax® or Mometamax™ and returned for reevaluation 2 - 8 days after treatment was completed.

Inclusion Criteria: Dogs must have concurrent bacterial and *Malassezia pachydermatis* infections in either one ear or both ears as determined by an ear swab. If both ears were infected, only the right ear was evaluated. Dogs with ear

mite infestations were excluded as well as those receiving concomitant local or systemic antibiotic, anti-inflammatory or antifungal therapy.

Parameters measured: A complete physical and otoscopic examination was made of both ears. The ears were cleaned with an ear cleansing solution free of antimicrobial and anti-inflammatory activity. Discomfort, pinna erythema, ear canal erythema, ear canal swelling and exudate (presence, quantity, type and odor) were evaluated prior to treatment and 8-10 days after completion of treatment. A quality of improvement survey was completed by the investigator and the owner at the second evaluation.

Pivotal Effectiveness Variables:

- Discomfort (mild/moderate, marked)
- Pinna erythema (mild/moderate, marked)
- Ear canal erythema (mild/moderate, marked)
- Ear canal swelling (mild/moderate, marked)
- Exudate - presence
 - quantity (mild/moderate, marked)
 - type (waxy, coffee ground or purulent),
 - odor (mild/moderate, marked)
- Owner final evaluation
- Investigator final evaluation

3. Results:

Discomfort: Discomfort was similarly alleviated by both treatments. At the final evaluation: 81% (100/123) and 89% (104/117) of the dogs in Otomax® and Mometamax™, respectively, showed no sign of discomfort.

Pinna Erythema: Upon final evaluation of pinna erythema, 86% of the Otomax® treated animals and 90% of the Mometamax™ treated animals had no sign of pinna erythema.

Ear Canal Erythema: Upon final evaluation of canal erythema, 73% of the Otomax® treated animals and 75% of the Mometamax™ treated animals had no sign of canal erythema.

Ear Canal Swelling: Upon final evaluation of canal swelling, 89% of the Otomax® treated animals and 92% of the Mometamax™ treated animals had no sign of canal swelling.

Exudate: More dogs treated with Otomax® did not have exudate present at the end of the study compared with dogs treated with Mometamax™ (72% versus 62% respectively). Twenty-seven percent (27%) of dogs treated with Otomax® had mild/moderate discharge at the end of the study compared to 38% of dogs treated with Mometamax™. Both treatments were similar in reducing purulent discharge. Four percent (4%) of dogs treated with Otomax® had purulent discharge after completing treatment compared with 3% of Mometamax™ treated

dogs. Twenty percent (20%) of dogs treated with Otomax® had waxy discharge present at the end of the study compared to 30% of Mometamax™ treated dogs. Dogs treated with either Otomax® or Mometamax™ were similar in reducing odor associated with otitis externa (89% for both treatment groups at the end of the study).

Owner and Investigator final evaluation: Both were similar for dogs treated with either Mometamax™ or Otomax®. Investigator overall evaluation rated Otomax® excellent or good in 92% of the cases compared to 91% of the Mometamax™ treated cases. Ninety-two percent (92%) of the dogs treated with Otomax® were rated overall excellent or good by owners compared to 95% of the dogs treated with Mometamax™.

4. Statistical Analysis:

A total of 240 (123 Otomax®, 117 Mometamax™) cases qualified for inclusion in the statistical analysis for effectiveness. A total of 287 (146 Otomax®, 141 Mometamax™) cases qualified for the safety evaluation. Data were pooled across the 13 investigators supplying qualified cases for effectiveness evaluation.

Because Otomax® was a positive control, the clinical responses of each treatment were evaluated utilizing confidence intervals. The confidence intervals were calculated by examining the improvement in clinical signs. 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 percentage of animals showing improvement with Otomax® was subtracted from the percentage of animals showing improvement with Mometamax™ Otic Suspension. A 90% confidence interval was constructed around this difference. The lower bound of this interval represents the minimum predicted level of effectiveness of the test article compared to the positive control (i.e., at worst, the percent improvement with Mometamax™ Otic Suspension may be as much as x% less than the percent improvement with Otomax®). Most of the clinical signs showed a percent improvement in the 90-99% range (see Table 1). For this reason, a lower bound of -10% for the 90% confidence interval was used as the criterion for determining that Mometamax™ Otic Suspension was "no worse than", i.e. "at least as good as" Otomax®.

Using this definition, four parameters did not meet the criteria for classification of "no worse than" (Table 1). These parameters include presence of exudate, type of exudate, quantity of exudate, and canal erythema. Canal swelling, with a lower bound of -10.6% as the difference between Mometamax™ and Otomax®, was very close to the criterion boundary. The remaining five parameters, pinna erythema, level of discomfort, odor of exudate, investigator evaluation and owner

evaluation satisfy the criteria and can be classified as "at least as good as" the positive control.

Table 1 Improvement in Clinical Variables

Variable	Mometamax	Otomax	Mometamax - Otomax		
	% Improvement	% Improvement	Difference	Lower 90% confidence bound	Upper 90% confidence bound
Discomfort	93.6% (n=110) ^a	88.7% (n=115)	4.9%	-3.0%	14.0%
Pinna Erythema	89.9% (n=69)	87.3% (n=71)	2.5%	-8.7%	15.8%
Canal Erythema	83.2% (n=113)	90.8% (n=120)	-7.6%	-14.9%	-0.4%
Canal Swelling	95.7% (n=94)	97.8% (n=90)	-2.0%	-10.6%	5.0%
Presence of Exudate	61.2% (n=71)	70.8% (n=120)	-9.6%	-20.9%	1.2%
Type of Exudate ^b	87.1% (n=31)	82.1% (n=28)	5.0%	-15.1%	28.4%
Quantity of Exudate	75.9% (n=116)	84.2% (n=120)	-8.3%	-18.7%	1.5%
Odor of Exudate	98.2% (n=109)	96.5% (n=115)	1.6%	-4.3%	8.7%
Investigator Evaluation	91.5% ^c (n=117)	91.9% ^c (n=123)	-0.4%	-8.9%	7.3%
Owner Evaluation	94.9% ^c (n=117)	91.8% ^c (n=122)	3.1%	-4.0%	11.3%

Notes:

^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 coffee grounds type of exudate on Day 0 and either none, waxy or coffee grounds type of exudate on Day 8 were excluded.

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

Time is a factor in the resolution of exudate; it can take more than 8-10 days for exudate to decrease by significant levels. Therefore, if we examine marked exudate, which is the extreme end of the quantity of exudate, and improvement from marked exudate, Mometamax™ Otic Suspension and Otomax® were similar in this parameter. This parameter satisfies the criteria and can be classified as "at least as good as".

Therefore, overall Mometamax™ Otic Suspension meets the criteria that it is at least as good as Otomax®.

5. Adverse Effects:

Nine dogs out of 287 cases (both Mometamax™ and Otomax®) exhibited adverse reactions (6 dogs treated with Otomax® and 3 dogs treated with Mometamax™).

Adverse reactions reported in dogs treated with Mometamax™ included: bilateral hyperemia of pinna (1 dog), vomiting during treatment (1 dog), and diarrhea (1 dog). Adverse reactions reported in dogs treated with Otomax® included: inflammation of pinna (1 dog), external ear canal inflammation (1 dog), diarrhea followed by constipation (1 dog), ataxia (1 dog), increased reluctance to accept treatment (1 dog), and deafness (1 dog). All 9 adverse reactions reverted to normal following cessation of treatment.

6. Conclusion:

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

V. ANIMAL SAFETY:

Target Animal Safety information for topical application of gentamicin sulfate and clotrimazole for the treatment of otitis externa in dogs is incorporated by reference to the original new animal drug application (NADA) for the otic product, Otomax® (NADA 140-896) which was approved on June 9, 1993.

A. *Six-Month Dermal Toxicity Study of SCH 32088 (Mometasone furoate Ointment) 0.1% in Dogs with Intact Skin:*

1. Purpose: To assess the dermal irritation and systemic toxicity of SCH 32088 (mometasone furoate) 0.1% after daily topical application to Beagle dogs with intact skin for six months.

2. Study Director: Robert E. Squibb, Ph.D.
Department of Pathology and Toxicology
Pharmaceutical Research Division
Schering Corporation
Lafayette, N. J. 07848

3. General Design:

Animals: 20 male and 20 female Beagle dogs approximately 11 months of age at the onset of the study. Body weight ranged from 6.4 to 11.8 kg. Dogs were randomly assigned to five groups (4/sex/group).

Dosage Form: Mometasone furoate 0.1% topical ointment.

Dosages:

Mometasone furoate 0.1%, 0.5 g/kg (12.5 X)
Mometasone furoate 0.1%, 1 g/kg (25 X)
Mometasone furoate 0.1%, 2 g/kg (50X)
Vehicle ointment, 2 g/kg
Untreated control, 0 g/kg

Route of Administration: Topical: Prior to dosing, and as needed throughout the study, each dog was prepared by clipping the skin of the flank and back free of hair. Medicated ointment or vehicle was applied daily to an area of skin comprising approximately 10% of the total body surface.

Study Duration: Daily application for six (6) months.

Pertinent Measurements/Observations: Dermal irritation, changes in physical appearance and behavior, physical examinations (including body temperature, respiratory and heart rates, blood pressure, electrocardiography), ophthalmic examinations, body weight, food consumption, hematological and blood chemistry data, gross and histological examination of selected organs at necropsy.

4. Results:

General Condition: Beginning at week 5, signs of muscle wasting were observed in one vehicle, two 1 g/kg and three 2 g/kg-dosed dogs. At the end of the study, two vehicle, three 0.5 g/kg, three 1 g/kg and four 2 g/kg-dosed dogs showed muscle wasting.

Physical Examination Data: No compound-related changes occurred in any of the groups during the course of the study.

Ophthalmology Data: No compound-related ocular changes occurred in any of the groups during the course of the study.

Dermal Response Data: Transient erythema was seen in 1/8 of the vehicle, 1/8 of the 0.5 g/kg, 2/8 of the 1 g/kg and 4/8 of the 2 g/kg-dosed animals. No edema was observed. Papules and/or pustules were common in all medicated groups and occasionally seen in the vehicle-treated group. Desquamation was occasionally seen in all medicated groups. Less than normal hair growth was seen at the application site in all medicated groups by week 9. One dog in the 2 g/kg group presented with a 12 cm circular band of reddish skin on its midback during week 14. The lesion disappeared by week 17. Some dogs from all three medicated groups presented with bluish discoloration between weeks 17 and 21. These areas eventually, paradoxically, resulted in new hair growth.

Body Weight & Food Consumption: All untreated dogs gained weight. Body weight changes among the medicated groups were variable (some animals gained slightly while others lost slightly). Food consumption was normal for all animals.

Hematology: Minimal to moderate decreases in absolute lymphocyte counts were observed for most animals in all three medicated groups. Two males in the 2 g/kg group experienced mild increases in neutrophil counts at weeks 5 and 25. No consistent compound-related changes were observed in red cell parameters.

Clinical Chemistry: Transient, slight increases in cholesterol, and triglycerides were observed in medicated and vehicle-dosed groups. Lipemia was only at the week 5 interval in 1/8 vehicle-treated animals and in some animals from the 0.5 g/kg and 2 g/kg medicated groups.

Urinalysis: Slight increases in 24-hour urine volume were noted at weeks 13 and 25 in all three medicated groups.

Gross Pathology: At necropsy, muscle wasting with a generalized absence of fat was evident in selected animals from all medicated and vehicle-treated groups. Adrenal glands and uteri in selected animals from the 1 g/kg and 2 g/kg groups were smaller than respective organs in most control dogs. Hepatic enlargement and/or discoloration were noted in one 0.5 g/kg-dosed female, one 1 g/kg-dosed male and in six 2 g/kg-dosed animals. The thymus appeared fatty in most animals from the 2 g/kg group. Skin thickness appeared less at the application site for medicated dogs in comparison to untreated and vehicle-dosed dogs. Skin thinning also occurred at the non-dosed areas for medicated dogs and indicated systemic absorption of the drug substance. Additional skin changes included tufts of coarse brown or black hairs and/or multiple white scars in the neck and/or lumbar regions of selected animals from the medicated groups.

Microscopic Pathology: Compound-related changes in the skin of medicated animals included minimal or slight atrophy of the epidermis, hair follicles and adnexa in five to six animals from each group. Thinning of the stratum corneum was noted in most animals including controls. All males and four females (2 animals from the 1 g/kg and two from the 2 g/kg groups) had some degree of adrenal cortical atrophy with the zona fasciculata being the most affected. Centrilobular hepatocytomegaly was evident in one male dog from each of the

three medicated groups. The majority of medicated males and selected medicated and vehicle-treated females exhibited fatty replacement of the bone marrow. Several males in all three medicated groups and all females in the 2 g/kg group had varying degrees of thymic involution. One male from the 2 g/kg group exhibited stomach mucosal erosion.

5. Conclusion:

Mometasone furoate ointment (0.1%) applied topically once daily to Beagle dogs for six months at approximately 12.5, 25 and 50 times the recommended label dose produced adverse effects typical of corticosteroid therapy. The doses administered in this study far exceed the recommended otic dose. For the labeled conditions of use, mometasone is safe for use on dogs in a 0.1 % formulation. Higher doses or prolonged use may result in clinical signs typical of corticosteroid therapy.

VI. HUMAN SAFETY:

Human Safety Relative to Food Consumption:

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. This drug is to be labeled for use in dogs which are non-food animals.

Human Safety Relative to Possession, Handling, and Administration:

There is a bolded statement on the front panel of the labeling components "Keep this and all drugs out of the reach of children."

VII. AGENCY CONCLUSIONS:

The data in support of this NADA comply with the requirements of Section 512 of the Act and Section 514 of the implementing regulations. The data demonstrate that Mometamax™ Otic Suspension for dogs, when used under labeled conditions of use, is safe and effective.

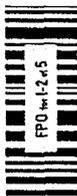
The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise and proper diagnosis are required to determine the presence of otitis externa and the presence of bacterial and/or yeast and to monitor the safe use of the product.

Under section 512(c)(2)(F)(ii) of the FFDCA, this approval for non food producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety required for the approval of the application and conducted or sponsored by the applicant.

VIII. LABELING (Attached):

- A. Package Insert
- B. Bottle label (15g, 30g and 215g)

Package Insert



F-23873605
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: *Staphylococcus intermedius*, *Staphylococcus aureus*, other *Staphylococcus* spp., *Pseudomonas aeruginosa*, *Proteus* spp., and *Escherichia coli*.

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

**PRODUCT
INFORMATION**

are handled through pharmacokinetic pathways 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 a clinical field trial, 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 canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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.

Clinical 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 Clinical 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 irreversible 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 a clinical field trial following treatment with MOMETAMAX Otic Suspension, inflammation of the pinna and diarrhea were observed in less than 1% of 141 dogs.

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 15 g and 30 g bottles (2 drops from the 215 g bottle) of MOMETAMAX Otic Suspension twice 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) twice daily into the ear canal. Therapy should continue for 7 consecutive days.

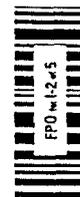
HOW SUPPLIED MOMETAMAX Otic Suspension is available in 15 g (NDC 0061-1246-04), 30 g (NDC 0061-1246-01), and 215 g (NDC 0061-1246-02) plastic bottles.

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

February 2000

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

Copyright © 2000, Schering-Plough Animal Health. All rights reserved. B-23873605



15 g Bottle

Label, Individual Carton, Carton of 12

NDC 0061-1246-04

15g

Mometamax™
(GENTAMICIN SULFATE, USP; MOMETASONE FUROATE MONOHYDRATE, USP; 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
23872404 200

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 4 drops of MOMETAMAX™ Otic Suspension twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops twice 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.
Copyright © 2000, Schering-Plough Animal Health Corp., Kenilworth, NJ 07033. All rights reserved. 23872404 200



FPO for 1-2 of 5

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

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle twice 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.

PS GLUE STRIP

PS

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

For otic use in dogs only.

Schering-Plough Animal Health Corp., Union, NJ 07083.
Copyright © 2000,
Schering-Plough Animal Health. All rights reserved.
23872404 200



NDC 0061-1246-04

15g

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

For otic use in dogs only.

Mometamax™
(GENTAMICIN SULFATE, USP; MOMETASONE FUROATE MONOHYDRATE, USP; 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



4-42 86%
FPO for UPC

N 0061-1246-04 X
3

01E3952

LOT & EXP

NO INK
CODE AREA
NO VARNISH



FPO for 1-2 of 5

005

NDC 0061-1246-04

**12 Bottles
15 g Each**

MometamaxTM

(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

MometamaxTM

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

For otic use in dogs only.



NO
+
VARNISH

DIE3953

GLUE STRIP

MometamaxTM

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

For otic use in dogs only.

Schering-Plough Animal Health Corp., Union, NJ 07083.
Copyright © 2000, Schering-Plough Animal Health.
All rights reserved.

23872501 2/00

LOT
EXP

CODE AREA
NO COLOR
NO VARNISH

PS

For otic use in dogs only.

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

MometamaxTM

12 Bottles/15 g Each

ORS



For otic use in dogs only.

Indications: MOMETAMAXTM Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

Description: Each gram of MOMETAMAXTM 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 MOMETAMAXTM Otic Suspension twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle twice 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.

ATE



30 g Bottle

Label, Individual Carton, Carton of 6

NDC 0061-1246-01 **30 g**

Mometamax™
(GENTAMICIN SULFATE, USP; MOMETASONE FUROATE MONOHYDRATE, USP; 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
2381209 200

CODE AREA

**HOLDING LINES
DO NOT PRINT**

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 4 drops of MOMETAMAX™ Otic Suspension twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops twice 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.

Copyright © 2000, Schering-Plough Animal Health Corp., Kenilworth, NJ 07033. All rights reserved. 2381209 200

FPO 1-2 of 5

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

NDC 0061-1246-01 **30 g**

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

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

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

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle twice 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.

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 Corp., Union, NJ 07083. Copyright © 2000. Schering-Plough Animal Health. All rights reserved. 24105300 200

Schering-Plough Animal Health

For otic use in dogs only.

4-4-2 80% FPO for UPC

N 0061-1246-01 X

DIE3970

NO VARNISH
CODE AREA

FPO 1-2 of 5

NDC 0061-1246-01

**6 Bottles
30 g Each**

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.

PANTONE COLORS

BLACK
PMS 201

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

DIE3969

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 8 drops from the bottle twice 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.

LOT
EXP

CODE AREA
NO COLOR
NO VARNISH

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

For otic use in dogs only.

Schering-Plough Animal Health
Corp., Union, NJ 07083.
Copyright © 2000, Schering-Plough
Animal Health. All rights reserved.
24105903 2/00



215 g Bottle

Label, Carton

NDC 0061-1246-02

215 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

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated
for the treatment of canine otitis externa associated with
yeast (*Malassezia pachydermatis*) and/or bacteria sus-
ceptible to gentamicin in dogs.

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

Dosage and Administration: The external ear canal
should be thoroughly cleaned and dried before treat-
ment. Verify that the eardrum is intact. For dogs weighing
less than 30 lbs, instill 2 drops of MOMETAMAX™ Otic
Suspension twice daily into the ear canal. For dogs
weighing 30 lbs or more, instill 4 drops twice 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.

Copyright © 2000, Schering-Plough
Animal Health Corp., Union, NJ 07083.
All rights reserved. 23873508 2/00

LOT & EXP

CODE AREA

For otic use in dogs only.

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

215 g

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 4 drops from the 215 g bottle twice 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.

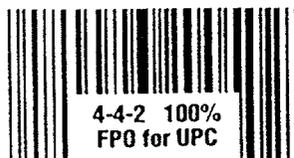
Schering-Plough Animal Health Corp.,
Union, NJ 07083.

Copyright © 2000, Schering-Plough Animal Health. All rights reserved.

24105709 2/00

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

For otic use in dogs only.



4-4-2 100%
FPO for UPC



For otic use in dogs only.

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

215 g

For otic use in dogs only.

Indications: MOMETAMAX™ Otic Suspension is indicated for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

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 twice daily into the ear canal. For dogs weighing 30 lbs or more, instill 4 drops from the 215 g bottle twice daily into the ear canal. Therapy should continue for 7 consecutive days.

Read accompanying directions carefully.

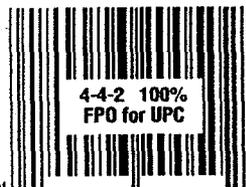
Store between 2° and 25°C (36° and 77°F).

Shake well before use.

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

Copyright © 2000, Schering-Plough Animal Health. All rights reserved.

24105709 2/00



4-4-2 100%
FPO for UPC

N 3 0061-1246-02 x

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

For otic use in dogs only.

NDC 0061-1246-02

215 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.

215 g

Mometamax™

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

For otic use in dogs only.

LOT & EXP

ON VARNISH

CODE AREA

ON INK



FPO 1-1-2-5