

Date of Approval: JAN 27 2005

## FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-287

### TRIPLEMAX

(gentamicin sulfate, USP, betamethasone valerate, USP, and clotrimazole, USP  
Ointment)

For otic use in dogs only

**TRIPLEMAX is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.**

Sponsored by:

Phoenix Scientific, Inc.

## ***1. GENERAL INFORMATION***

- a. File Number: ANADA 200-287
- b. Sponsor: Phoenix Scientific, Inc.  
3915 S. 48<sup>th</sup> St. Terrace  
St. Joseph, MO 64503
- Drug Labeler Code: 059130
- c. Established Name: Gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP
- d. Proprietary Name: TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment)
- e. Dosage Form: Ointment
- f. How Supplied: 10-gram, 20-gram and 215-gram plastic bottles.
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each gram of TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP, ointment) contains gentamicin sulfate USP equivalent to 3 mg gentamicin base; betamethasone valerate, USP equivalent to 1 mg betamethasone; and 10 mg clotrimazole, USP in a mineral oil based system containing a plasticized hydrocarbon gel.
- i. Route of Administration: Topical
- j. Species/Class: Dogs
- k. Recommended Dosage: Instill 2 drops of TRIPLEMAX twice daily to the ear canal of dogs weighing less than 30 lbs. Instill 4 drops twice daily into the ear canal of dogs weighing 30 lbs or more. Therapy should continue for 7 consecutive days.

- l. Pharmacological Category: Antibacterial, anti-inflammatory, and antifungal.
- m. Indications: TRIPLEMAX is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.
- n. Pioneer Product: OTOMAX Ointment; gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP; NADA 140-896; Schering-Plough Animal Health Corp.
- o. Effect of Supplement: This supplement provides for an additional package size, 20-gram fill in a 30 mL bottle. The bottle will be the same LDPE as the approved 15 mL bottle, and the plug, dropper and cap will be the exact same closure as the approved package.

## **2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic\* version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc., was granted a waiver from the requirements for an *in vivo* bioequivalence study for the generic product TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and Clotrimazole, USP Ointment). The generic product is administered as an ointment, contains the same active ingredient in the same concentration and dosage form as the

pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product OTOTMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment), the subject of Schering-Plough Animal Health Corp., NADA 140-896, was approved on June 9, 1993.

**3. 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 ANADA.

Human Warnings are provided on the product label as follows: "For Otic Use in Dogs Only. Keep this and all drugs out of reach of children."

**4. AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment), when used under its proposed conditions of use, is safe and effective for its labeled indications.

**5. ATTACHMENTS:**

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-287:

TRIPLEMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment);  
20 gram bottle label  
Package insert

Pioneer Labeling for NADA 140-896:

OTOMAX (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP Ointment);  
Package insert  
15 gram bottle label  
15 gram bottle individual carton

NDC 59130-716-37

**TripleMax™**  
 (GENTAMICIN SULFATE, USP,  
 BETAMETHASONE VALERATE, USP  
 AND CLOTRIMAZOLE, USP  
 OINTMENT)

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

ANADA 200-287, Approved by FDA.  
 NET CONTENTS: 20 g



For otic use in dogs only.  
 Indications: TripleMax™ (Gentamicin Sulfate, USP,  
 Betamethasone Valerate, USP and Clotrimazole, USP  
 Ointment) is indicated for the treatment of canine acute  
 and chronic otitis externa associated with yeast  
 (*Malassezia pachydermatis*, formerly *Pityrosporum canis*)  
 and/or bacteria susceptible to gentamicin.  
 Each gram contains: gentamicin sulfate USP equivalent to  
 3 mg gentamicin base; betamethasone valerate, USP  
 equivalent to 1 mg betamethasone; and 10 mg  
 clotrimazole, USP in a mineral oil-based system con-  
 taining a plasticized hydrocarbon gel.  
 Read accompanying directions carefully.  
 Store between 2° and 25°C (36° and 77°F).  
 Shake well before use.  
 800004

Manufactured by  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64503

Lot No.  
 Exp. Date

Iss. 4-04

NDC 59130-716-37

**TripleMax™**  
 (GENTAMICIN SULFATE, USP,  
 BETAMETHASONE VALERATE, USP  
 AND CLOTRIMAZOLE, USP  
 OINTMENT)

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

ANADA 200-287, Approved by FDA.  
 NET CONTENTS: 20 g



For otic use in dogs only.  
 Indications: TripleMax™ (Gentamicin Sulfate, USP,  
 Betamethasone Valerate, USP and Clotrimazole, USP  
 Ointment) is indicated for the treatment of canine acute  
 and chronic otitis externa associated with yeast  
 (*Malassezia pachydermatis*, formerly *Pityrosporum canis*)  
 and/or bacteria susceptible to gentamicin.  
 Each gram contains: gentamicin sulfate USP equivalent to  
 3 mg gentamicin base; betamethasone valerate, USP  
 equivalent to 1 mg betamethasone; and 10 mg  
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 Read accompanying directions carefully.  
 Store between 2° and 25°C (36° and 77°F).  
 Shake well before use.  
 800004

Manufactured by  
 Phoenix Scientific, Inc.  
 St. Joseph, MO 64503

Lot No.  
 Exp. Date

Iss. 4-04

ANADA 200-287, Approved by FDA

# TripleMax™

(GENTAMICIN SULFATE, USP, BETAMETHASONE VALERATE, USP AND CLOTRIMAZOLE, USP OINTMENT)

## 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 TripleMax™ (Gentamicin Sulfate, USP, Betamethasone Valerate, USP Clotrimazole, USP Ointment) contains gentamicin sulfate USP equivalent to 3 mg gentamicin base; betamethasone valerate, USP equivalent to 1 mg betamethasone; and 10 mg clotrimazole, USP in a mineral oil based ointment containing a plasticized hydrocarbon gel.

## PHARMACOLOGY:

**Gentamicin:** Gentamicin sulfate is an aminoglycoside antibiotic active against a wide variety of pathogenic gram-negative and gram-positive bacteria. *In vitro* tests have determined that gentamicin is bactericidal and inhibits normal protein synthesis in susceptible microorganisms. Specifically, gentamicin is active against the following organisms commonly isolated from canine ears: *Staphylococcus aureus*, other *Staphylococcus* spp., *Pseudomonas aeruginosa*, *Proteus* spp., and *Escherichia coli*.

**Betamethasone:** Betamethasone valerate is a synthetic adrenocorticoid for dermatologic use. Betamethasone valerate, a synthetic analog of prednisolone, has a high degree of corticosteroid activity and a slight degree of mineralocorticoid activity. Betamethasone valerate, the 17-valerate ester of betamethasone, has been shown to provide anti-inflammatory and anti-pruritic activity in the topical management of corticosteroid-responsive otitis externa.

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 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 pathogenic dermatophytes and yeasts. The primary action of clotrimazole is to inhibit cell wall synthesis, 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* (*Pityrosporum canis*). Resistance to clotrimazole is very rare among the fungi that cause superficial mycoses.

In an induced otitis externa infected with *Malassezia pachydermatis*, 1% clotrimazole in the Gentamicin Sulfate Betamethasone Valerate, USP and Clotrimazole, USP Ointment vehicle 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 cellular 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-Betamethasone-Clotrimazole:** By virtue of its three active ingredients, TripleMax™ has antibacterial, anti-inflammatory, and antifungal activity.

In component efficacy studies, the compatibility and additive effect of each of the components were demonstrated. In clinical field trials, Gentamicin Sulfate, USP, Betamethasone Valerate, USP and Clotrimazole, USP Ointment was effective in the treatment of otitis externa associated with bacteria and *Malassezia pachydermatis*. Gentamicin Sulfate, USP, Betamethasone Valerate, USP and Clotrimazole, USP Ointment reduced discomfort, redness, swelling, exudate, and odor and exerted a strong antimicrobial effect.

**INDICATIONS:** TripleMax™ is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

**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 TripleMax™ 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 TripleMax™ immediately and flush the ear thoroughly with a non-ototoxic solution.

Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate offspring. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which 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:** Identification of infecting organisms should be made either by microscopic roll smear evaluation or by culture as appropriate. Antibiotic susceptibility of the pathogenic organism(s) should be determined prior to use of this preparation.

If overgrowth of nonsusceptible bacteria, fungi, or yeasts occur, or if hypersensitivity develops, treatment should be discontinued and appropriate therapy instituted.

Administration of recommended doses of TripleMax™ beyond 7 days may result in delayed wound healing.

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 overdose 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. 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.

**TOXICOLOGY:** Clinical and safety studies with Gentamicin Sulfate, USP, Betamethasone Valerate, USP, and Clotrimazole, USP Ointment have shown a wide safety margin at the recommended dose level in dogs (see **PRECAUTIONS/SIDE EFFECTS**).

### **SIDE EFFECTS:**

**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.

**Betamethasone:** Side effects such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia, polyuria have occurred following the use of parenteral or systemic synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs and cats.

Cushing's syndrome in dogs has been reported with 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.

**DOSAGE AND ADMINISTRATION:** The external ear should be thoroughly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable non-irritating solutions. Excessive hair should be clipped from the treatment area. After verifying that eardrum is intact, instill 2 drops of TripleMax™ twice daily into the ear canal of dogs weighing less than 30 lbs. Instill 4 drops twice daily into the ear canal of dogs weighing 30 lbs. or more. Massage external ear canal carefully after instillation to ensure appropriate distribution of medication. Therapy should continue for 7 consecutive days.

**HOW SUPPLIED:** TripleMax™ (Gentamicin Sulfate, USP, Betamethasone Valerate, USP, and Clotrimazole, USP Ointment) is available in 10 gram, 20 gram and 215 gram plastic bottles.

Store between 2° and 25° C (36° and 77° F).  
800004

Shake well before use.  
Rev. 4

Manufactured by  
Phoenix Scientific, Inc.  
St. Joseph, MO 64503

**Otomax**<sup>®</sup> (GENTAMICIN SULFATE, USP,  
BETAMETHASONE VALERATE, USP, AND CLOTRIMAZOLE, USP OINTMENT)

**WARNINGS** The use of OTOMAX ointment 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 OTOMAX ointment immediately and flush the ear canal thoroughly with a nontoxic 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 which 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** Identification of infecting organisms should be made either by microscopic roll smear evaluation or by culture as appropriate. Antibiotic susceptibility of the pathogenic organism(s) should be determined prior to use of this preparation.

If overgrowth of nonsusceptible bacteria, fungi, or yeasts occur, or if hypersensitivity develops, treatment should be discontinued and appropriate therapy instituted.

Administration of recommended doses of OTOMAX ointment beyond 7 days may result in delayed wound healing.

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.

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.

**TOXICOLOGY** Clinical and safety studies with OTOMAX ointment have shown a wide safety margin at the recommended dose level in dogs (see **PRECAUTIONS/SIDE EFFECTS**).

**SIDE EFFECTS**

**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.

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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.

**DOSAGE AND ADMINISTRATION** The external ear should be thoroughly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area. After verifying that the eardrum is intact, instill 4 drops from the 7.5 g and 15 g tube, and 12.5 g and 30 g bottle (2 drops from the 215 g bottle) of OTOMAX ointment twice daily into the ear canal of dogs weighing less than 30 lbs. Instill 8 drops from the 7.5 g and 15 g tube, and 12.5 g and 30 g bottle (4 drops from the 215 g bottle) twice daily into the ear canal of dogs weighing 30 lbs or more. Massage external ear canal carefully after instillation to ensure appropriate distribution of medication. Therapy should continue for 7 consecutive days.

**HOW SUPPLIED** OTOMAX ointment is available in 7.5 g (NDC 0061-0387-01) and 15 g (NDC 0061-0387-02) tubes as well as in 215 g (NDC 0061-0387-03), 30 g (NDC 0061-0387-08), and 12.5 g (NDC 0061-0387-09) plastic bottles.

Store between 2° and 25°C (36° and 77°F). Shake well before use when using the 215 g bottle, 30 g bottle, and 12.5 g bottle.

Made in Canada. March 2000 81-475845  
Schering-Plough Animal Health Corp., Union, NJ 07083  
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F 17489143  
NADA #140-896, Approved by FDA.

**PRODUCT INFORMATION**

**Otomax**<sup>®</sup> (GENTAMICIN SULFATE, USP,  
BETAMETHASONE VALERATE, USP, AND CLOTRIMAZOLE, USP OINTMENT)

**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 OTOMAX ointment contains gentamicin sulfate, USP equivalent to 3 mg gentamicin base; betamethasone valerate, USP equivalent to 1 mg betamethasone, 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 pathogenic 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. Specifically, gentamicin is active against the following organisms commonly isolated from canine ears. *Staphylococcus aureus*, other *Staphylococcus* spp., *Pseudomonas aeruginosa*, *Proteus* spp., and *Escherichia coli*

**Betamethasone:** Betamethasone valerate is a synthetic adrenocorticoid for dermatologic use. Betamethasone, an analog of prednisolone, has a high degree of corticosteroid activity and a slight degree of mineralocorticosteroid activity. Betamethasone valerate, the 17-valerate ester of betamethasone, has been shown to provide anti-inflammatory and antipruritic activity in the topical management of corticosteroid-responsive otitis externa

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 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 pathogenic dermatophytes and yeasts. 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* (*Pityrosporum canis*). Resistance to clotrimazole is very rare among the fungi that cause superficial mycoses.

In an induced otitis externa infected with *Malassezia pachydermatis*, 1% clotrimazole in the OTOMAX vehicle 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-Betamethasone-Clotrimazole:** By virtue of its three active ingredients, OTOMAX ointment has antibacterial, anti-inflammatory, and antifungal activity.

In component efficacy studies, the compatibility and additive effect of each of the components were demonstrated. In clinical field trials, OTOMAX ointment was effective in the treatment of otitis externa associated with bacteria and *Malassezia pachydermatis*. OTOMAX ointment reduced discomfort, redness, swelling, exudate, and odor, and exerted a strong antimicrobial effect.

**INDICATIONS** OTOMAX ointment is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

**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.



NDC 0061-0387-03

15 g

**Otomax**<sup>®</sup> (GENTAMICIN SULFATE, USP; BETAMETHASONE VALERATE, USP; AND CLOTRIMAZOLE, USP OINTMENT)

Keep Out of Reach of Children.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA #140-896, Approved by FDA.

Schering-Plough Animal Health

For otic use in dogs only.

Indications: OTOMAX<sup>®</sup> Ointment is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

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

Read accompanying directions carefully. Store between 2° and 25°C (36° and 77°F).

Made in Canada. See crimp for Lot No. and Exp. Date.

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17451229 Rev. 3/00  
1705 81-254542

RW  
3/07  
✓



DX3

LOT

NDC 0061-0387-03

15 g



N 0061-0387-03 5  
3

**Otomax**<sup>®</sup> (GENTAMICIN SULFATE, USP; BETAMETHASONE VALERATE, USP; AND CLOTRIMAZOLE, USP OINTMENT)

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

Dosage and Administration: The external ear should be properly cleaned and dried before treatment. Remove foreign material, debris, crusted exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the treatment area. After verifying that the eardrum is intact, instill 4 drops of OTOMAX ointment twice daily into the ear canal of dogs weighing less than 30 lbs. Instill 8 drops twice daily into the ear canal of dogs weighing 30 lbs or more. Massage external ear canal carefully after instillation to ensure appropriate distribution of medication. Therapy should continue for 7 consecutive days.

Read accompanying directions carefully.

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

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Animal Health Corp.,  
Union, NJ 07083.  
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17858033 Rev 3/00

Schering-Plough Animal Health

Client

Patient

Directions: Apply \_\_\_\_\_ drops twice daily for 7 days.

2

**Otomax**<sup>®</sup> (GENTAMICIN SULFATE, USP; BETAMETHASONE VALERATE, USP; AND CLOTRIMAZOLE, USP OINTMENT)

81-155445

