Indications for use: GBC Ointment™ is used in 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.
St. Joseph, MO 64503
1. GENERAL INFORMATION:
   a. ANADA Number: 200-287
   b. Sponsor: Phoenix Scientific, Inc.
      3915 S. 48th St. Terrace
      St. Joseph, MO 64503
      21 CFR 510.600: Labeler Code: 059130
   c. Established Name: Gentamicin Sulfate, Betamethasone Valerate
      and Clotrimazole Ointment
   d. Trade/Proprietary Name: GBC Ointment™
   e. Dosage Form: Ointment
   f. How Supplied: 10 gram and 215 gram plastic bottles
   g. How Dispensed: Rx
   h. Amount of Active Ingredients: Each gram: 3 mg gentamicin base, 1 mg
      betamethasone and 10 mg clotrimazole, USP
      in mineral oil base system.
   i. Route of Administration: Topical
   j. Species: Dogs
   k. Labeled Dosage and Administration:
      Instill 2 drops of GBC Ointment™ twice
      daily into ear canal of dogs weighing less
      than 30 lbs and 4 drops of GBC Ointment™
      twice daily into the ear canal of dogs
      weighing 30 lbs or more.
1. Indications for Use: Treatment of canine acute and chronic otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin

m. Pharmacological Category: Antibacterial, Antifungal

n. Pioneer Product: Otomax® manufactured by Schering-Plough Animal Health (NADA 140-896)

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 drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA Sponsor shows 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 conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on May 5, 1997, from the requirement of an in vivo bioequivalence study for GBC Ointment™. The generic and pioneer products contain the same active and inactive ingredients in a similar formulation as the pioneer. The pioneer product, Otomax®, the subject of Schering-Plough Animal Health’s NADA 140-896 was approved on June 9, 1993.

3. HUMAN SAFETY:

This drug is indicated for use only 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.”
“For Otic Use in Dogs Only”
4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that GBC Ointment™ when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. Attachments:

Labeling:

Pioneer Labeling for NADA 140-896:
Otomax®-7.5, 12.5 g, 15g, 30g, 215g

Generic Labeling for ANADA 200-287

(AmTech’s) GBC™- 10 gram and 215 gram bottles
Insert

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.
**OTOMAX® (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 2 mg gentamicin; 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 interfering with 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 mineralocorticoid activity. Betamethasone valerate, the 17-valerate ester of betamethasone, has been shown to provide anti-inflammatory and antipruritic activity in the topical management of inflammatory dermatoses. 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 (Phycomycetes candid). 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 otitis externa associated with bacteria and Malassezia pachydermatis. OTOMAX ointment is effective for the reduction of discomfort, redness, swelling, exudate, and odor and exerted a strong antimicrobial effect.

**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. I am not to be used in dogs with known perforation of eardrums.

**COMPONENTS:**

- **Gentamicin Sulfate:** USP equivalent to 2 mg gentamicin
- **Betamethasone Valerate:** USP equivalent to 1 mg betamethasone
- **Clotrimazole:** USP equivalent to 10 mg

**BASE:** A mineral oil-based system containing a plasticized hydrocarbon gel.
Otomax® (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 (e.g., geriatric). The hearing deficit is usually temporary. If hearing or vestibular dysfunction is noted during the course of treatment, discontinuous use of OTOMAX ointment immediately and flush the ear canal thoroughly with a nonirritating solution.

Corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring after maternal withdrawal. Treatment should not 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 adverse corticoid overdosage which include sodium retention, potassium loss, fluid retention, weight gain, polyuria, and/or polydysuria. 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 pretreated 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 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 cilia of the 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.

Betamethasone: Minor Side effects such as ear itch, ootitis externa, pruritus, polyuria, polydipsia, and polyuria have occurred following the use of parenteral or topical corticosteroid preparations in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs and cats.

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, itching, paroxysms, edemas, 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, crust, exudates, etc., with suitable nonirritating solutions. Excessive hair should be clipped from the external ear. After verifying that the tympanic membrane is intact, install 4 drops from the 7.5 g and 15 g bottle, 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. Install 6 drops from the 7.5 g and 15 g bottle, and 12.5 g and 30 g bottle (6 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). Shake well before use when using the 215 g bottle, 30 g bottle, and 12.5 g bottle.

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

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E-17485143

Schering-Plough Animal Health Care, Union, NJ 07083
Otomax®
(ARCOTACETIC SULFATE,
USP; BETAMETHASONE
VALERATE, USP; AND
CLITROMAZOLE, 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.

NACLX #143-996, Approved by FDA.

Otomax®
(ARCOTACETIC SULFATE,
USP; BETAMETHASONE
VALERATE, USP; AND
CLITROMAZOLE, USP
OINTMENT)

For otic use in dogs only,
Indications: OTOMAX® contains sulfa,
USP; betamethasone valerate, USP; and clotrimazole.
USP ointment is indicated for the treat-
ment of canine otitis externa and chronic it-
itis externa associated with yeast (Malassezia pachydermatis), fever (Pseudomonas aeruginosa), and/or bacteria (e.g., Pseudomonas aeruginosa).

For otic use in

Dosage and Administration: The
external ear should be properly
cleaned and dried before treatment.

Cleanse and dry the external ear;

then clip the fur in the treatment
area. After inserting the applicator
in the ear canal of dogs weighing less than 20
lb (9 kg), or cats weighing 5 lb (2.3
kg) or more, massage the external ear
canal carefully after application to
ensure appropriate distribution of medica-
tion. Therapy should continue for 7
consecutive days.

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

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NDC 006-0387-02

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Science. Schering-Plough.

Science. Schering-Plough.

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For otic use in dogs only.

Indications: OTOMAX® (gentamicin sulfate USP, betamethasone valerate, USP, and clotrimazole. USP ointment) is indicated for the treatment of canine acute and chronic otic lesions 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.

Dosage and Administration: The external ear should be properly cleaned and dried before treatment. Remove foreign material, debris, crusty 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. For dogs weighing 30 lbs or more, instill 8 drops twice daily into the ear canal. 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).

Shake well before use.
For otic use in dogs only.

Indications: OTOMAX® ointment is indicated for the treatment of canine and feline otitis externa associated with yeast (Malassezia pachydermatis), bacteria, Pseudomonas aeruginosa, and/or Malassezia pachydermatis.

Each gram container contains: gentamicin, USP, equivalent to 2 mg gentamicin base; betamethasone valerate, USP, equivalent to 1 mg betamethasone; and 10 mg clobetasol propionate, USP in a mineral oil-based system containing a steroidal hydrocarbon gel.

Dissolution and Administration: The external ear should be properly cleansed and dried before treatment. Packette for use in sensitive areas. Excessive hair should be clipped from the treatment area. After thoroughness, the ointment is inserted into the ear canal of dogs weighing 20 lbs or more. Massage external ear canal carefully after instillation to ensure adequate distribution of medication. Therapy should continue for 7 consecutive days.

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

Keep Out of Reach of Children.

NADA #4-0-688, Approved by FDA.

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

Scherer-Pouach Animal Health

NDC 031-037-03

150

For otic use in dogs only.

Indications: OTOMAX® ointment is indicated for the treatment of canine and feline otitis externa associated with yeast (Malassezia pachydermatis), bacteria, Pseudomonas aeruginosa, and/or Malassezia pachydermatis.

Each gram container contains: gentamicin, USP, equivalent to 2 mg gentamicin base; betamethasone valerate, USP, equivalent to 1 mg betamethasone; and 10 mg clobetasol propionate, USP in a mineral oil-based system containing a steroidal hydrocarbon gel.

Dissolution and Administration: The external ear should be properly cleansed and dried before treatment. Packette for use in sensitive areas. Excessive hair should be clipped from the treatment area. After thoroughness, the ointment is inserted into the ear canal of dogs weighing 20 lbs or more. Massage external ear canal carefully after instillation to ensure adequate distribution of medication. Therapy should continue for 7 consecutive days.

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

Keep Out of Reach of Children.

NADA #4-0-688, Approved by FDA.

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

Scherer-Pouach Animal Health
Otomax® (gentamycin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP)

**For otic use in dogs only.**

**Keep Out of Reach of Children.**

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

*Made in Canada*  
All rights reserved.*

For otic use in dogs only.
Indications: OTOMAX® ointment is indicated for the treatment of canine acute and chronic otitis externa associated with yeast (Malassezia pachydermatis, formerly Pityrosporum ovale) 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 hydroxypropyl cellulose gel.

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 ear drum is intact, instill 2 drops of OTOMAX ointment 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.

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 ear use in dogs only.

Made in Canada.

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174591610 Rev 9/00
81-482142

3 0061-0387-01 1
For otic use in dogs only.

Indications: GBC Ointment™ (Gentamicin Sulfate, USP, Betamethasone Valerate, USP and Clotrimazole, USP Ointment) is indicated for the treatment of canine acute and chronic otitis externa associated with yeasts (Malassezia pachydermatis, formerly Pityrosporum canis) and/or bacteria susceptible to gentamicin.

Each gram contains: gentamicin sulfate USP equivalent to 5 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). Shake well before use.

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

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.
GBC OINTMENT™
(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 200-207, Approved by FDA.

NET CONTENTS: 215 g

For use in dogs only.

Indications: GBC Ointment™ (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 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 non-irritating solutions. Excessive hair should be clipped from the treatment area. After verifying that the eardrum is intact, instill 2 drops of GBC Ointment™ (Gentamicin Sulfate, USP, Betamethasone Valerate, USP and Clotrimazole, USP Ointment) 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.

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

NETCOMTENTS: 215g

Read accompanying directions carefully.

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

MANUFACTURED BY:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lor No.
Exp. Date

800004

CUSTOMER PROOF & CHECK CAREFULLY!

Customer: Phoenix Scientific
P.O. #: Lisa


LABEL: GBC Ointment 215 grams

SIZE: 4.5" x 7"

PATTERN VARNISH: water

COLORS: black 1797 red

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: 
Date approved: 

MANUFACTURED BY:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No. 
Exp. Date

800004