VETROPOLYCIN- bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment Dechra Veterinary Products

Vetropolycin[®] (neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment) Veterinary Ophthalmic Ointment

STERILE - ANTIBACTERIAL

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

DESCRIPTION: Each gram contains bacitracin zinc 400 units, neomycin sulfate 5 mg (equiv. to 3.5 mg neomycin base), polymyxin B sulfate 10,000 units, in a base of white petrolatum and mineral oil.

INDICATIONS: For the treatment of superficial bacterial infections of the eyelid and conjunctiva in dogs and cats when due to organisms susceptible to the antibiotics contained in the ointment.

Laboratory tests should be conducted including *in vitro* culturing and susceptibility tests on samples collected prior to treatment.

DOSAGE AND ADMINISTRATION: Apply a thin film over the cornea three to four times daily in dogs and cats. The area should be properly cleansed prior to use. Foreign bodies, crusted exudates, and debris should be carefully removed prior to use.

WARNING: Do not use this product as a pre-surgical ocular lubricant. Adverse reactions of ocular irritation and corneal ulceration have been reported in association with such use.

Serious hypersensitivity (anaphylactic) reactions have been reported in cats within 4 hours of application of antibiotic ophthalmic preparations. Some of these reactions have resulted in death.

HUMAN WARNINGS: Keep out of reach of children.

PRECAUTIONS: Sensitivity to this ophthalmic ointment is rare, however, if a reaction occurs, discontinue use of the preparation. The prolonged use of antibiotic-containing preparations may result in overgrowth of nonsusceptible organisms including fungi.

Appropriate measures should be taken if this occurs.

If infection does not respond to treatment in two or three days, the diagnosis and therapy should be reevaluated.

Care should be taken to not contaminate the applicator tip of the tube during the application of the preparation. Do not allow the applicator tip to come in contact with any tissue.

ADVERSE REACTIONS: Itching, burning or inflammation may occur in animals sensitive to the product. Discontinue use in such cases.

For a copy of the Safety Data Sheet (SDS), or to report adverse reactions, call Dechra Veterinary Products at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or http://www.fda.gov/AnimalVeterinary/SafetyHealth

ACTIONS: The three antibiotics present in Vetropolycin (neomycin and polymyxin B sulfates and bacitracin zinc ophthalmic ointment) Veterinary Ophthalmic Ointment provide a broad spectrum of activity against the gram-positive and gram-negative bacteria commonly involved in superficial infections of the eyelid and conjunctiva.

Bacitracin is effective against gram-positive bacteria including hemolytic and non-hemolytic streptococci and staphylococci.

Resistant strains rarely develop.

Neomycin is effective against both gram-positive and gram-negative bacteria including staphylococci, *Escherichia coli* and *Haemophilus influenzae* and many strains of *Proteus* and *Pseudomonas*.

Polymyxin B is bactericidal to gram-negative bacteria especially *Pseudomonas*. No resistant strains have been found to develop *in vivo*.

STORAGE INFORMATION: KEEP TIGHTLY CLOSED.

STORE AT 15°-25°C (59° -77°F).

HOW SUPPLIED: 3.5 g (1/8 oz) sterile tamper proof tubes.

NDC 17033-028-38

NADA 065-016, Approved by FDA

Manufactured for:

Dechra Veterinary Products 7015 College Boulevard, Suite 525 Overland Park, KS 66211 USA

Rev. 03/18 Ini0912

PRINCIPAL DISPLAY PANEL - 3.5 g Tube Carton

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STERILE - ANTIBACTERIAL

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. This product is not for use in food producing animals. NADA 065-016, Approved by FDA

NET WT 3.5 g (1/8 oz)

Dechra



| VETROPOLYCIN | | | | |
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| bacıtracın zınc, neomycın sulfat | te, and polymyxin b sulfate ointment | | | |
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| Product Information | | | | |
| Product T ype | PRESCRIPTION ANIMAL DRUG | Ite m | Code (Source) | NDC:17033-028 |
| Route of Administration | OPHTHALMIC | | | |
| | | | | |
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| | | | | |
| Active Ingredient/Active M | Ioiety | | | |
| U | Ioiety gredient Name |] | Basis of Strength | Strength |
| Ing | | | Basis of Strength ACITRACIN | Strength 400 [USP'U] in 1 g |
| Ing Bacitracin Zinc (UNII: 89 Y4M234E | gredient Name | В | C C | |
| Ing Bacitracin Zinc (UNII: 89Y4M234E Neomycin Sulfate (UNII: 057Y6266 | gredient Name ES) (BACITRACIN - UNII:58H6RWO52I) | B | ACITRACIN | 400 [USP'U] in 1 g |
| Ing Bacitracin Zinc (UNII: 89Y4M234E Neomycin Sulfate (UNII: 057Y6266 | gredient Name ES) (BACITRACIN - UNII:58H6RWO52I) 693) (NEOMYCIN - UNII:116QD7X297) | B | ACITRACIN EOMYCIN | 400 [USP'U] in 1 g 5 mg in 1 g |
| Ing Bacitracin Zinc (UNII: 89Y4M234E Neomycin Sulfate (UNII: 057Y6266 | gredient Name ES) (BACITRACIN - UNII:58H6RWO52I) 693) (NEOMYCIN - UNII:116QD7X297) | B | ACITRACIN EOMYCIN | 400 [USP'U] in 1 g 5 mg in 1 g |
| Ing Bacitracin Zinc (UNII: 89Y4M234E Neomycin Sulfate (UNII: 057Y6266 | gredient Name ES) (BACITRACIN - UNII:58H6RWO52I) 693) (NEOMYCIN - UNII:116QD7X297) | B | ACITRACIN EOMYCIN | 400 [USP'U] in 1 g 5 mg in 1 g |

| mineral oil (UNII: T5L87 | Г28FGP) | | | | |
|--------------------------|--|----------|----------------------|----|--------------------|
| petrolatum (UNII: 4T6H1 | 2BN9U) | | | | |
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| | | | | | |
| Packaging | | | | | |
| # Item Code | Package Description | Marketin | g Start Date | Ma | arketing End Date |
| 1 NDC:17033-028-38 | 1 in 1 CARTON | | | | |
| 1 | 3.5 g in 1 TUBE | | | | |
| | | | | | |
| | | | | | |
| Marketing Information | | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | | Marketing End Date |
| NADA | NADA065016 | | 04/10/2014 | | |
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Labeler - Dechra Veterinary Products (362142734)

| Establishment | | | | | |
|-------------------------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Altaire Pharmaceuticals, Inc. | | 786790378 | MANUFACTURE | | |
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Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|----------------------------|
| Xellia Pharmaceuticals Inc. | | 529171201 | API MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|----------------------------|
| Pharmacia and Upjohn Company | | 618054084 | API MANUFACTURE |

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-------------|----------------------------|
| Xellia Pharmaceuticals AS | | 30 58 14345 | API MANUFACTURE |

Revised: 12/2018

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