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

Vetropolycin® HC
(neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone acetate 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 (equivalent to 3.5 mg neomycin base), polymyxin B sulfate 10,000 units, hydrocortisone acetate 10 mg (1%), in a base of white petrolatum and mineral oil.

INDICATIONS: It may be used in acute or chronic conjunctivitis, when caused by organisms susceptible to the antibiotics contained in this 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.

CONTRAINDICATIONS: Ophthalmic preparations containing corticosteroids are contraindicated in the treatment of those deep, ulcerative lesions of the cornea where the inner layer (endothelium) is involved, in fungal infections and in the presence of viral infections.

WARNINGS: All topical ophthalmic preparations containing corticosteroids with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until the infection is under control and corneal regeneration is well under way.

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.

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection 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.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have resulted in cleft palate in offspring.

Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia, and anasarca.

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 re-evaluated.

Animals under treatment with this product should be observed for usual signs of corticosteroid overdose which include polydipsia, polyuria and occasionally an increase in weight. Use of

corticosteroids, depending on dose, duration, and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in unusually stressful situations. Care should be taken not to contaminate the applicator tip during the administration of the preparation.

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

SAP and SGPT (ALT) enzyme elevations, polydipsia and polyuria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

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 overlapping spectra of these three antibiotics provide effective bactericidal action against most commonly occurring gram-positive and gram-negative bacteria associated with infections of the eyes. The range of bactericidal activity encompasses many bacteria which are, or have become, resistant to other antibiotics, notably *Pseudomonas* and *Staphylococcus.*

In susceptible organisms, resistance rarely develops, even on repeated or prolonged usage. Hydrocortisone acetate exerts a marked anti-inflammatory action at the tissue level and effectively suppresses inflammation in many disorders of the anterior segment of the eye. Local application to the eye often gives rapid relief of pain and photophobia, particularly in lesions of the cornea. The combined anti-inflammatory and antimicrobial activity of Vetropolycin HC (neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone acetate ophthalmic ointment) Veterinary Ophthalmic Ointment permits effective management of many disorders of the anterior segment of the eye in which combined activity is needed.

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 17033-030-38

NADA 065-015, 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

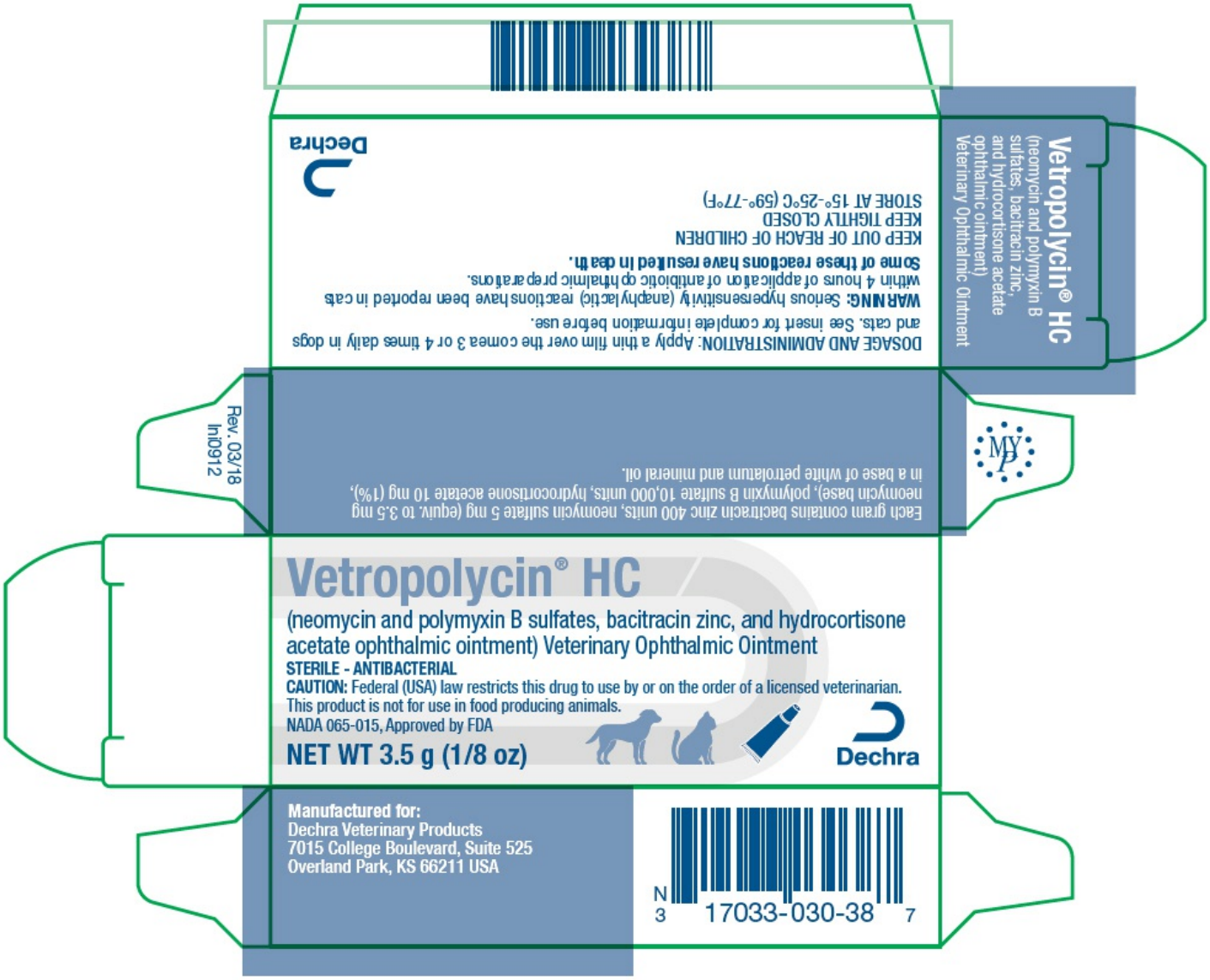
Vetropolycin® HC
(neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone acetate ophthalmic ointment) Veterinary Ophthalmic Ointment

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

NADA 065-015, Approved by FDA

NET WT 3.5 g (1/8 oz)

Dechra



VETROPOLYCIN HC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate, and hydrocortisone acetate ointment

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:17033-030
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Bacitracin Zinc (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [USP'U] in 1 g
Neomycin Sulfate (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	5 mg in 1 g

Polymyxin B Sulfate (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g
Hydrocortisone Acetate (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	Hydrocortisone Acetate	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
mineral oil (UNII: T5L8T28FGP)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17033-030-38	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	NADA065015	04/10/2014	

Labeler - Dechra Veterinary Products (362142734)

Establishment

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

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		305814345	API MANUFACTURE

Revised: 6/2019 Dechra Veterinary Products