NEOMYCIN AND POLYMYXIN B SULFATES, AND BACITRACIN ZINC- neomycin sulfate, polymyxin b sulfate and bacitracin zinc ointment
Akorn Animal Health, Inc.

Neomycin and Polymyxin B Sulfates and
Bacitracin Zinc Ophthalmic Ointment (Sterile)
– VETERINARY

ANADA 200-553, Approved by FDA

DESCRIPTION:

Each gram contains: polymyxin B sulfate 10,000 units, bacitracin zinc 400 units, neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base) in a white petrolatum base, q.s.

ACTIONS:

Polymyxin B is one of a group of closely related substances produced by various strains of *Bacillus polymyxa*. The activity of polymyxin B is sharply restricted to gram-negative bacteria. Neomycin, isolated from *Streptomyces fradiae*, has antibacterial activity *in vitro* against a wide range of gram-negative and gram-positive organisms. Bacitracin, an antibiotic substance derived from cultures of *Bacillus subtilis* (Tracy), exerts antibacterial action *in vitro* against a variety of gram-positive and a few gram-negative organisms.

INDICATIONS:

This product is indicated for the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to one or more of the antibiotics contained in the ointment.

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

PRECAUTIONS:

If irritation develops discontinue treatment with this drug. If there is no response to treatment in 2 to 3 days, discontinue treatment and re-evaluate diagnosis. Prolonged use may result in overgrowth of nonsusceptible organisms, including fungi.

Care should be taken not to contaminate the applicator tip during administration of the preparation.

ADVERSE REACTIONS:

Adverse reactions, such as itching, burning, or inflammation may occur in animals sensitive to this product.

DOSAGE AND ADMINISTRATION:

Properly cleanse area to be treated. Foreign bodies, crusted exudates and debris should be carefully removed. Express a small quantity of ointment into the conjunctival sac beneath the lower eyelid three or four times daily. After application hold the eyelids shut for a short time so that a thin film of ointment covers the cornea.

HOW SUPPLIED:

NDC 59399-135-35

Tube of 3.5 g (1/8 oz) with ophthalmic tip.

STORAGE:

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temp].

KEEP OUT OF REACH OF CHILDREN.

Not for Human Use.

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

Warning: 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.

AKORN
Animal Health
Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045
VTNP00N Rev. 02/15

Principal Display Panel Text for Container Label:

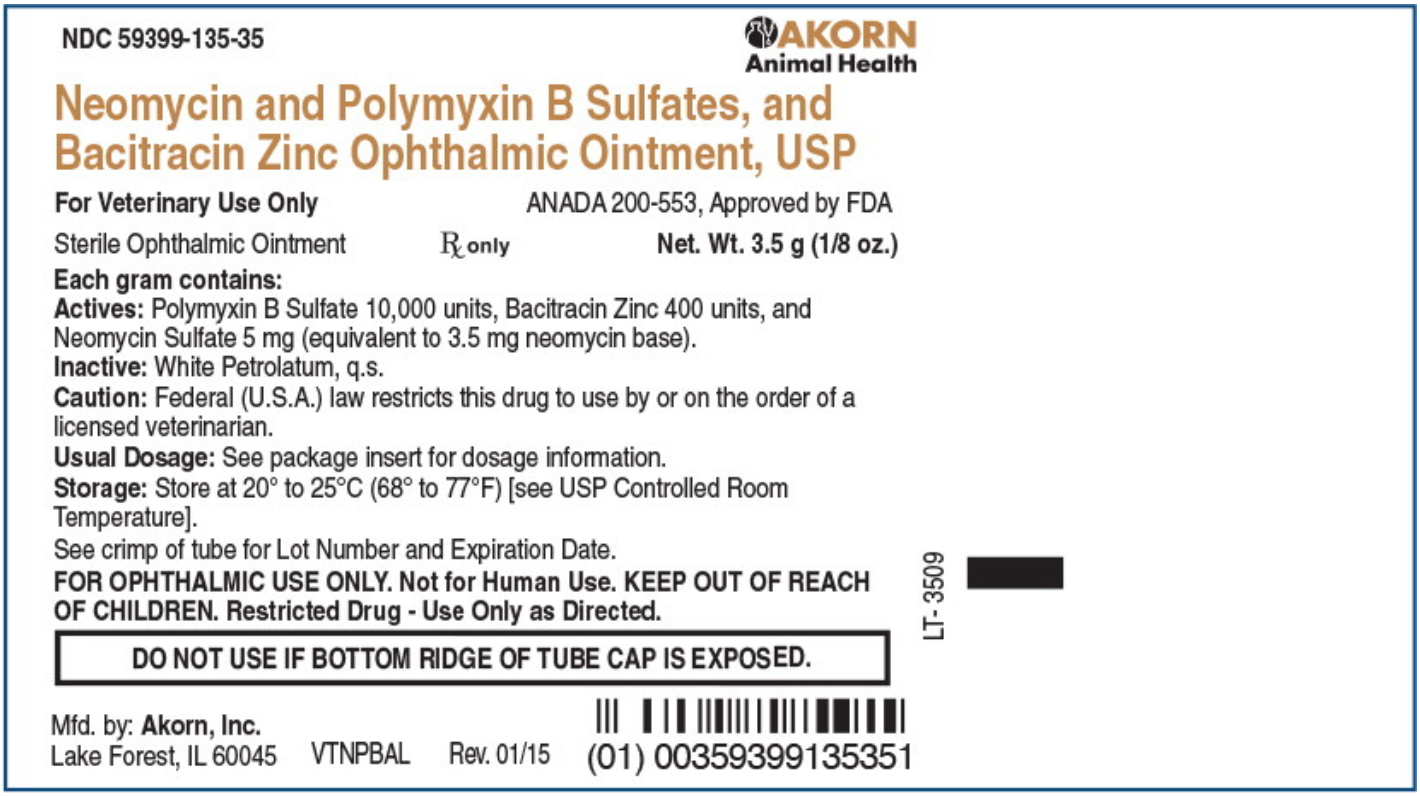
NDC 59399-135-35 Akorn Animal Health

Neomycin and Polymyxin B Sulfates, and

Bacitracin Zinc Ophthalmic Ointment, USP

For Veterinary Use Only ANADA 200-553, Approved by FDA

Sterile Ophthalmic Ointment Rx only Net. Wt. 3.5 g (1/8 oz.)



Principal Display Panel Text for Carton Label:

Sterile Ophthalmic Ointment NDC 59399-135-35

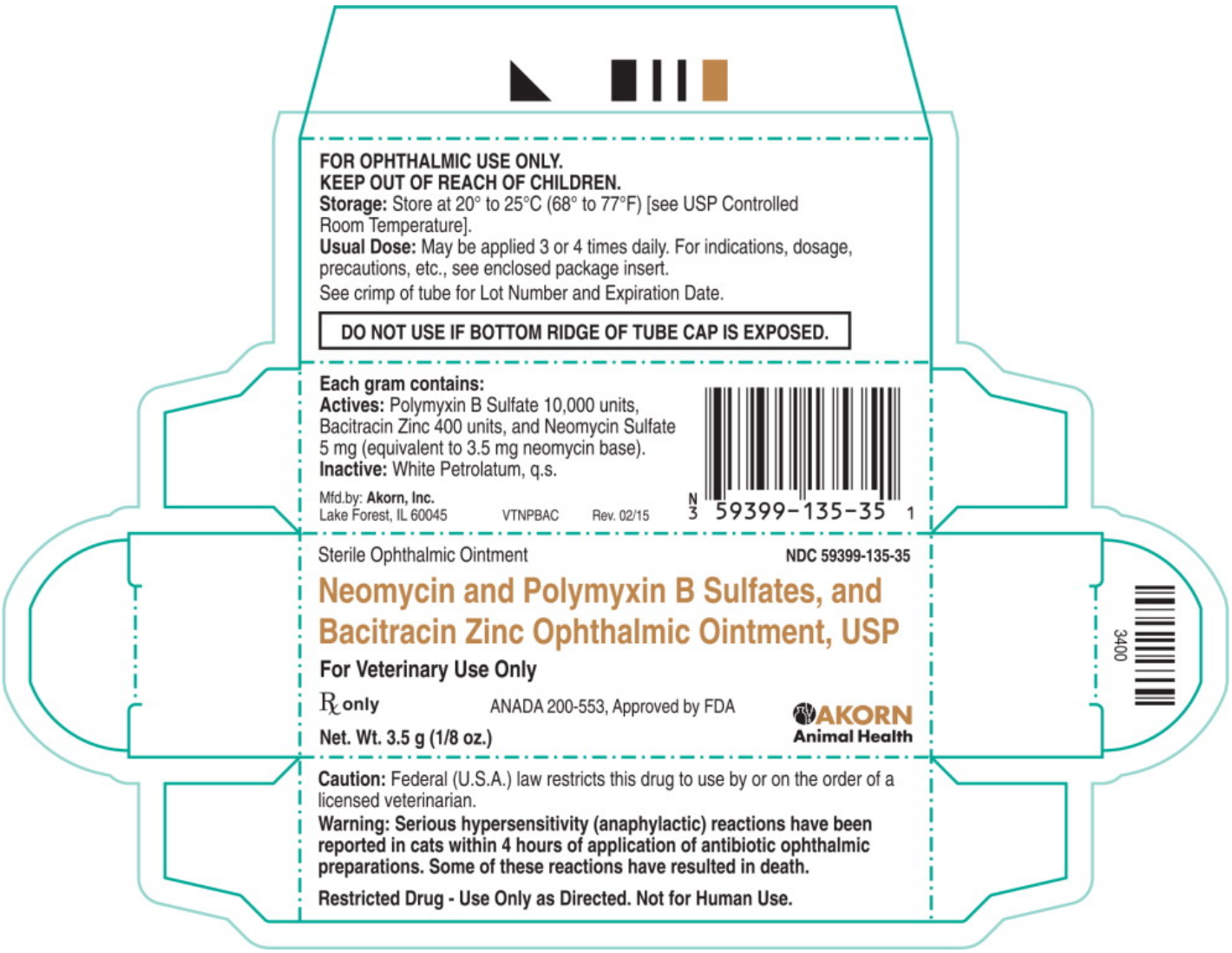
Neomycin and Polymyxin B Sulfates, and

Bacitracin Zinc Ophthalmic Ointment, USP

For Veterinary Use Only

Rx only ANADA 200-553, Approved by FDA

Net. Wt. 3.5 g (1/8 oz.) Akorn Animal Health Logo



NEOMYCIN AND POLYMYXIN B SULFATES, AND BACITRACIN ZINC

neomycin sulfate, polymyxin b sulfate and bacitracin zinc ointment

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:59399-135
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Neomycin Sulfate (UNII: 057Y626693) (Neomycin - UNII:I16QD7X297)	Neomycin	3.5 mg in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B	10000 [USP'U] in 1 g
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	400 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59399-135-35	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
ANADA	ANADA200553	07/30/2015	

Labeler - Akorn Animal Health, Inc. (078876357)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		603980319	MANUFACTURE, ANALYSIS, STERILIZE, PACK, LABEL

Revised: 9/2015 Akorn Animal Health, Inc.