AK-POLY-BAC- bacitracin zinc and polymyxin b sulfate ointment
Akorn, Inc.

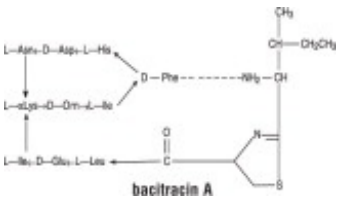
Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP, Sterile

Rx only

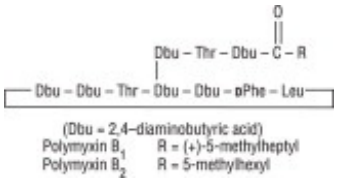
DESCRIPTION:

Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment is a sterile antimicrobial ointment for ophthalmic use.

Bacitracin zinc is the zinc salt of bacitracin, a mixture of related cyclic polypeptides (mainly bacitracin A) produced by the growth of an organism of the licheniformis group of *Bacillus subtilis* var Tracy. It has a potency of not less than 40 bacitracin units per mg. The structural formula for bacitracin A is:



Polymyxin B Sulfate is the sulfate salt of polymyxin B_1 and B_2 which are produced by the growth of *Bacillus polymyxa* (Prazmowski) Migula (Fam. Bacillaceae). It has a potency of not less than 6,000 polymyxin B units per mg, calculated on an anhydrous basis. The structural formulae are:



Each gram contains: Bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, white petrolatum and mineral oil.

CLINICAL PHARMACOLOGY:

Polymyxin B attacks gram-negative bacilli, including virtually all strains of *Pseudomonas aeruginosa* and *H influenzae* species.

Bacitracin is active against most gram-positive bacilli and cocci including hemolytic streptococci.

INDICATIONS AND USAGE:

For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by organisms susceptible to bacitracin zinc and polymyxin B sulfate.

CONTRAINDICATIONS:

This product is contraindicated in those individuals who have shown hypersensitivity to any of its components.

WARNINGS:

Ophthalmic ointments may retard corneal healing.

PRECAUTIONS:

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

DOSAGE AND ADMINISTRATION:

Apply the ointment every 3 or 4 hours for 7 to 10 days, depending on the severity of the infection.

HOW SUPPLIED:

Bacitracin Zinc and Polymyxin B Sulfate ophthalmic ointment USP, sterile, each gram contains bacitracin zinc equal to 500 bacitracin units and polymyxin B sulfate equal to 10,000 polymyxin B units, in a tube of 3.5 g (1/8 oz) with ophthalmic tip.

NDC 17478-238-35

STORAGE:

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

Akorn
Manufactured By: Akorn, Inc.
Lake Forest, IL 60045
AKP00N
Rev. 06/16

Principal Display Panel Text for Container Label:

NDC 17478-238-35 Akorn

AK-POLY-BAC™

brand of Bacitracin Zinc and Polymyxin B Sulfate

Ophthalmic Ointment USP

For Ophthalmic Use Only. Sterile

Rx only Net Wt 3.5 g (1/8 oz)

NDC 17478-238-35 Akorn

AK-POLY-BAC™

brand of Bacitracin Zinc and Polymyxin B Sulfate Ophthalmic Ointment USP

For Ophthalmic Use Only. **Sterile**

Rx only Net Wt 3.5 g (1/8 oz)

Each Gram Contains: Bacitracin zinc equal to 500 bacitracin units, polymyxin B sulfate equal to 10,000 polymyxin B units, white petrolatum and mineral oil.

Usual Dosage: See package insert for dosage information.

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

LT-2649-4

Mfg by:
Akorn, Inc., Lake Forest, IL 60045
AKPAL Rev. 11/08

(01) 00317478238355

Principal Display Panel Text for Carton Label:

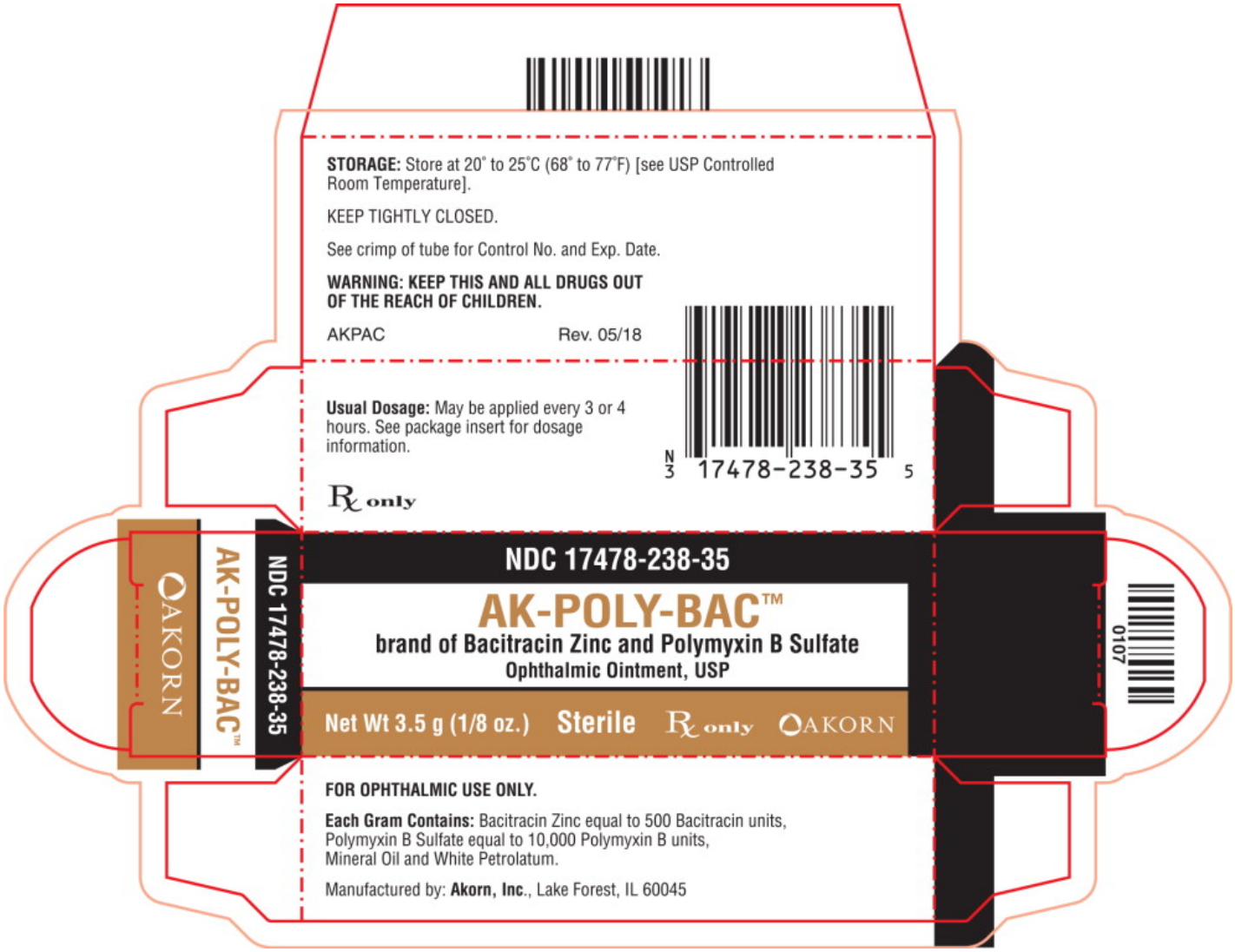
NDC 17478-238-35

AK-POLY-BAC™

brand of Bacitracin Zinc and Polymyxin B Sulfate

Ophthalmic Ointment, USP

Net Wt 3.5 g (1/8 oz.) Sterile Rx only Akorn Logo



AK-POLY-BAC

bacitracin zinc and polymyxin b sulfate ointment

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17478-238
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	500 [USP'U] in 1 g
Polymyxin B Sulfate (UNII: 19371312D4) (Polymyxin B - UNII:J2VZ07J96K)	Polymyxin B	10000 [USP'U] 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:17478-238-35	1 in 1 CARTON	05/08/2006	
1		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064028	05/08/2006	

Labeler - Akorn, Inc. (117696770)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc		117696840	MANUFACTURE(17478-238) , ANALYSIS(17478-238) , STERILIZE(17478-238) , PACK(17478-238) , LABEL(17478-238)

Revised: 10/2020 Akorn, Inc.