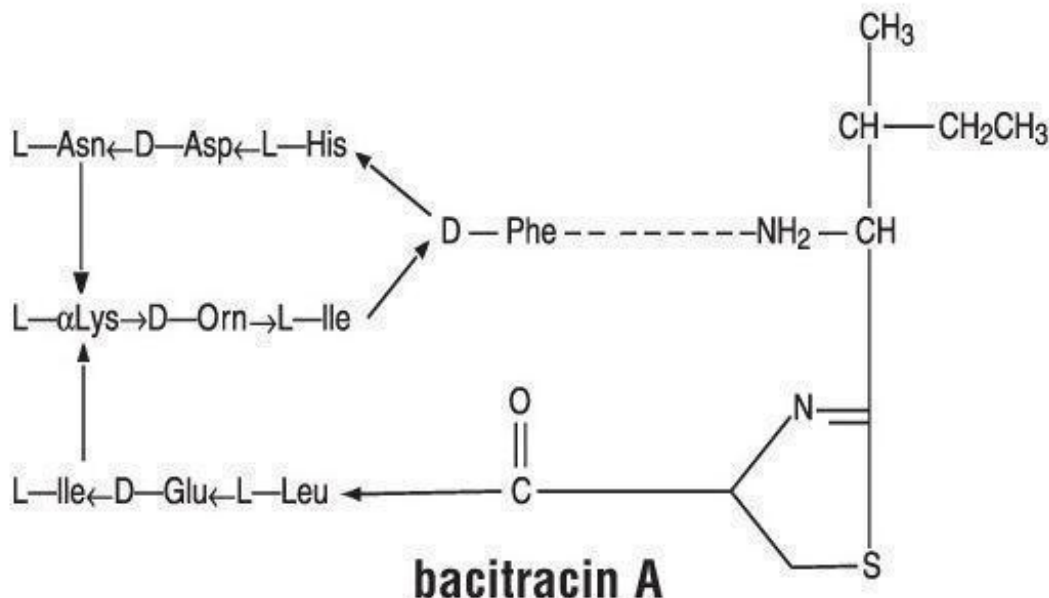


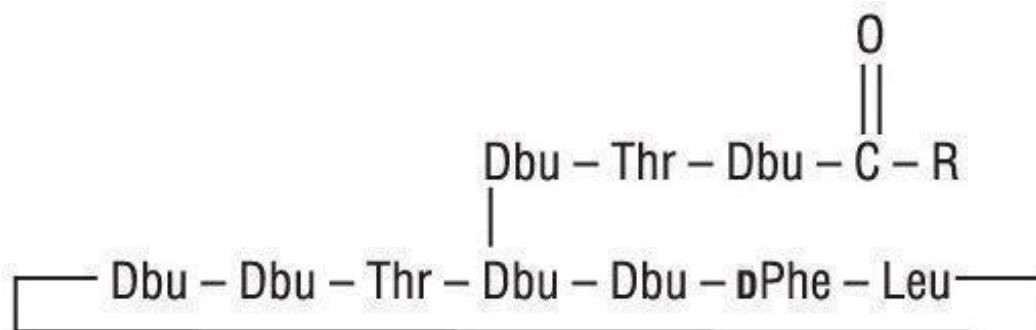
**AK-POLY-BAC- ak-poly-bac ointment  
DIRECT RX**

**AK-POLY-BAC**

**DESCRIPTION SECTION**



Polymyxin B Sulfate is the sulfate salt of polymyxin B1 and B2 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:



(Dbu = 2,4-diaminobutyric acid)  
 Polymyxin B<sub>1</sub>      R = (+)-5-methylheptyl  
 Polymyxin B<sub>2</sub>      R = 5-methylhexyl

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 SECTION**

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 & USAGE SECTION**

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 SECTION**

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

## **WARNINGS SECTION**

Ophthalmic ointments may retard corneal healing.

## **PRECAUTIONS SECTION**

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 & ADMINISTRATION SECTION**

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

## **HOW SUPPLIED SECTION**

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. 11/08

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 (1/8oz.)

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



**AK-POLY-BAC**

ak-poly-bac ointment

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:61919-989(NDC:17478-238)
<b>Route of Administration</b>	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:61919-989-35	3.5 g in 1 CARTON; Type 0: Not a Combination Product	01/01/2015	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA064028	01/01/2014	

**Labeler** - DIRECT RX (079254320)

## Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-989)

Revised: 1/2020

DIRECT RX