

LEADER FIRST AID ANTIBIOTIC- bacitracin zinc, and polymyxin b sulfate ointment
Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients (in each gram)	Purpose
Bacitracin 500 units.....	First aid antibiotic
Polymyxin B 10,000 units.....	First aid antibiotic

Uses

first aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- you need to use longer than 1 week
- condition persists or gets worse
- rash or other allergic reaction develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area
- apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Other information

- Store at 20° to 25°C (68° to 77°F)
- Lot No. & Exp. Date: see box or see crimp of tube

Inactive ingredients

white petrolatum base

Distributed by:

Cardinal Health
 Dublin, Ohio 43017
 www.myleader.com
 1-800-200-6313
 Made in Korea



LEADER FIRST AID ANTIBIOTIC
 bacitracin zinc, and polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	500 [USPU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	10000 [USPU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0111-1	1 in 1 CARTON		
1		28 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
OTC monograph final	part333B	03/09/2016	

Labeler - Cardinal Health (097537435)