ANTIBIOTIC APPLICATION- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
CMC Group, Inc.

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.

Antibiotic Application

Drug Facts

Active ingredients (in each gram)

Bacitracin zinc (bacitracin 400 units)

Neomycin sulfate (neomycin 3.5mg)

Polymyxin B sulfate (polymyxin B 5,000 units)

Purpose

First aid antibiotic

Use

- First aid to help prevent infection in minor cuts, scrapes, and burns.

Warnings

For external use only.

Do not use

• in the eyes • over large areas of the body • if you are allergic to any of the ingredient • longer than 1 week unless directed by a doctor.

Ask a doctor before use if you have

• deep or punture wounds • animal bites • serious burns.

Stop use and ask a doctor if

• the condition persists or gets worse • a 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.

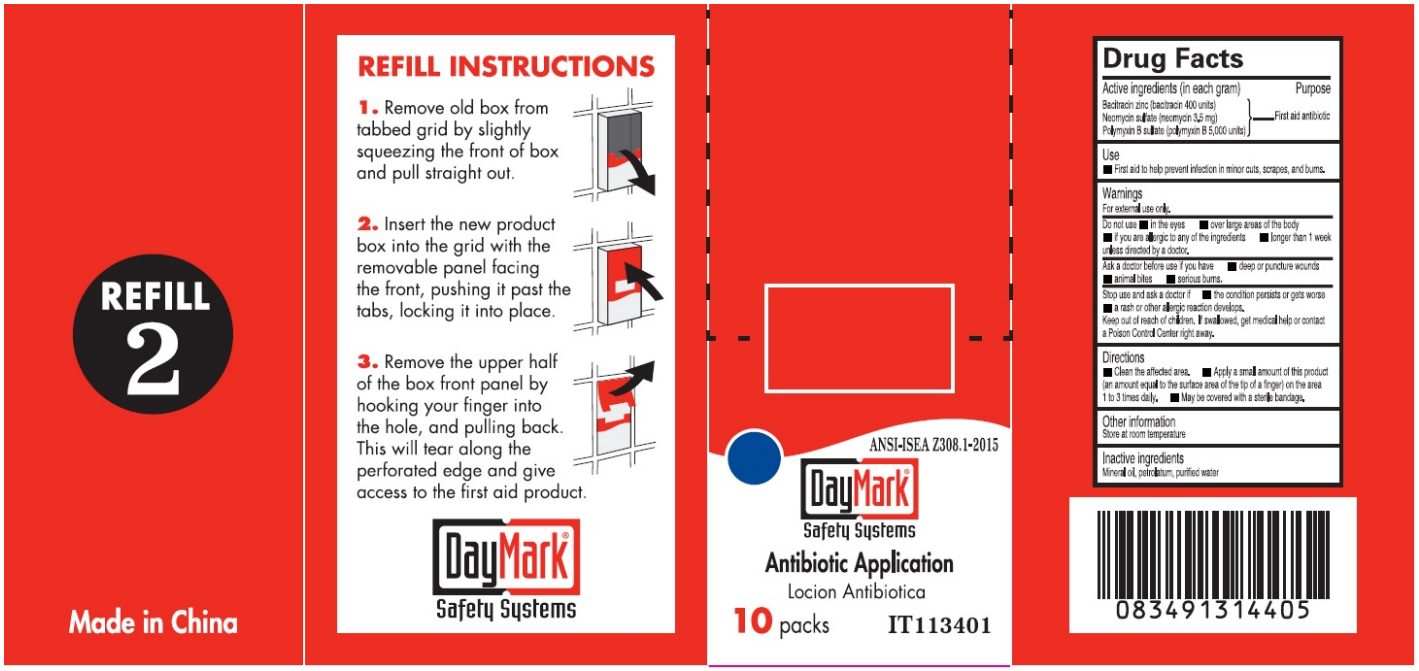
Other information

Store at room temperature

Inactive ingredients

Mineral oil, petrolatum, purified water

Package Labeling:



ANTIBIOTIC APPLICATION

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49687-0013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
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	5000 [iU] in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:49687-0013-0	10 in 1 KIT	08/06/2016	
1		0.9 g in 1 PACKAGE; 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	08/06/2016	

Labeler - CMC Group, Inc. (117201448)

Revised: 1/2021 CMC Group, Inc.