LEADER TRIPLE ANTIBIOTIC AND PAIN RELIEF- bacitracin, neomycin, polymyxin b, pramoxine hcl ointment Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Triple Antibiotic Ointment + Pain Relief Drug Facts

Active ingredients (in each gram)

Bacitracin zinc 500 units

Neomycin sulfate equivalent to 3.5 mg of neomycin base

Polymyxin B 10,000 units as polymyxin B sulfate

Pramoxine HCl 10 mg

Purpose

First aid antibiotic

External analgesic

Uses

first aid to help prevent infection and for temporary relief of pain or discomfort 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
- symptoms persist for more than 1 week, or clear up and occur again within a few days
- 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. (1-800-222-1222)

Directions

- adults and children 2 years of age or older:
- 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
- children under 2 years of age: ask a doctor

Other information

store at 20-25°C (68-77°F)

Inactive ingredient

white petrolatum

Questions or comments?

1-800-719-9260

Principal Display Panel

Maximum Strength

Triple Antibiotic Ointment + Pain Relief

Bacitracin Zinc | Neomycin Sulfate | Polymyxin B Sulfate | Pramoxine HCl

COMPARE TO NEOSPORIN® + PAIN RELIEF active ingredients

First Aid Antibiotic Pain Relieving Ointment

Soothes Cuts, Scrapes and Burns

100% Money Back Guarantee

NET WT 1 OZ (28 g)



LEADER TRIPLE ANTIBIOTIC AND PAIN RELIEF

bacitracin, neomycin, polymyxin b, pramoxine hcl ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0390
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN	500 [USP'U] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	3.5 mg in 1 g	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ 07J96K)	POLYMYXIN B	10000 [USP'U] in 1 g	
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics			
Color	YELLOW (Translucent)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0390-1	1 in 1 CARTON	12/13/2018	
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	12/13/2018	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)