BACITRAYCIN PLUS- bacitracin zinc and pramoxine hydrochloride ointment First Aid Research Corp

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.

First Aid Research Max Strength Bacitraycin Plus Ointment 1oz w/ Pramoxine HCl Vertical (89992V, 2019)

Active ingredients (in each gram) Purposes

Bacitracin zinc 500 units......First aid antibiotic

Parmoxine HCl 10 mg.....External analgesic

Uses

- first aid to help prevent infection and for the temporary relief of pain in minor:
- cuts
- scrapes
- burns

For external use only

Do no use

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

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
- symptoms persist for more than 1 week, or clear up and occur again within a few days
- condition persists or gets worse
- redness, irritation, swelling, or pain persists or increases
- rash or other allergic reactin develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

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

Other information

• store at room temperature 20-25°C (68-77°F)

Inactive ingredients aloe vera oil, petrolatum

FIRST AID RESEARCH CORP.

Dirtributed by:

Jupiter, FL 33478 Made in China





BACITRAYCIN PLUS

bacitracin zinc and pramoxine hydrochloride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75983-056
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PRAMO XINE HYDRO CHLO RIDE (UNII: 88 AYB8 67L5) (PRAMO XINE - UNII: 068 X84E056)	PRAMO XINE HYDRO CHLO RIDE	10 mg in 1 g	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	500 [USP'U] in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
METHYLPARABEN (UNII: A2I8C7HI9T)		
PETROLATUM (UNII: 4T6H12BN9U)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75983-056-01	1 in 1 BOX	01/09/2019		
1		28 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:75983-056-02	1 in 1 BOX	01/09/2019		
2		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	01/09/2019			

Labeler - First Aid Research Corp (089405927)

Revised: 10/2020 First Aid Research Corp