

FAMILY WELLNESS- bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
FRONT PHARMACEUTICAL PLC

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)

Bacitracin 400 units

Neomycin 3.5 mg

Polymyxin B 5,000 units

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Uses first aid to help prevent infection in minor:

-uses -scrapes -burns

Warnings

For external use only.

Do not use

- if you are allergic to any of the ingredients in this product
- in contact with the eyes or mucous membranes
- 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

- symptoms persist for more than 7 days, the condition persists or gets worse
- symptoms clear up and then occur again within a few days
- a rash or other allergic reaction occurs

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

Directions

Adults and children 2 years of age and older:

- clean the affected area
- apply a small amount of this product to affected area 1 to 3 times daily
- May be covered with a sterile bandage.

Children under 2 years of age: ask a doctor before use.

Other information store at room temperature 68 - 77 F (20-25 C).

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST

Inactive ingredients mineral oil, petrolatum



FAMILY WELLNESS

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69571-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	.41 g in 100 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	.0035 g in 100 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	.52 g in 100 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:69571-003-02	1 in 1 BOX	02/22/2017	
1	NDC:69571-003-01	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	02/22/2017	

Labeler - FRONT PHARMACEUTICAL PLC (530897792)

Establishment

Name	Address	ID/FEI	Business Operations
FRONT PHARMACEUTICAL PLC		530897792	manufacture(69571-003)

Revised: 2/2017

FRONT PHARMACEUTICAL PLC