

TRIPLE ANTIBIOTIC - bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment
Morales Distributors 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.

Triple Antibiotic

Active ingredients (in each gram)

Bacitracin Zinc 400 units

Neomycin Sulfate 3.5mg

Polymyxin B Sulfate 5,000 units

Purposes

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

Ask a doctor before use if you have

- serious burns
- deep or puncture wounds
- animal bites

When using this product

- do not use in the eyes
- do not apply over large areas of the body

Stop use and ask a doctor if

- you need to use more 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.

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
 - may be covered with a sterile bandage
- children under 2 years of age: ask a doctor

Other information

store at 59 degrees to 77 degrees Fahrenheit

Inactive ingredients

Liquid paraffin, Cethanol, Squalane, Lanolin, Petrolatum, Tocopheryl acetate

Package label

NDC NO. 53210-1004-0

First Aid Prevent Infection

Cuts Scrapes Burns

Maximum Strength

Help Prevent Infection in Minor Cuts, Scrapes and Burns

Soothing Ointment

Original

TRIPLE ANTIBIOTIC

Polymyxin B Sulfate-Bacitracin Zinc-Neomycin Sulfate

Net 1 oz(28.3g)

Exclusively distributed by:

Morales Distributors, Inc

Mayaguez, P.R. 00682

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Original Neosporin (R)

Made in Korea



NDC NO. 53210-1004-0



First Aid Prevent Infection

+ *Cuts* + *Scrapes* + *Burns*

*Help Prevent Infection
in Minor Cuts, Scrapes & Burns*

SOOTHING OINTMENT

SOOTHING OINTMENT *Original*

TRIPLE ANTIBIOTIC

Polymyxin B Sulfate-Bacitracin Zinc-Neomycin Sulfate

NET 1 oz(28.3g)

LOT & EXP.

SOOTHING OINTMENT

TRIPLE ANTIBIOTIC

Polymyxin B Sulfate-Bacitracin Zinc-Neomycin Sulfate



Exclusively distributed by:
Morales Distributors, Inc
Mayaguez, P.R. 00682



TRIPLE ANTIBIOTIC

Polymyxin B Sulfate-Bacitracin Zinc-Neomycin Sulfate

Drug Facts	Drug Facts(continued)
<p>Active ingredients (in each gram)</p> <p>Bacitracin Zinc 400 units.....First aid antibiotic Neomycin Sulfate 3.5mg.....First aid antibiotic Polymyxin B Sulfate 5,000 units.....First aid antibiotic</p>	<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
<p>Uses First aid to help prevent infection in minor: ■ cuts ■ scrapes ■ burns</p>	<p>Directions</p> <ul style="list-style-type: none"> ■ 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 ■ may be covered with a sterile bandage ■ children under 2 years of age: ask a doctor
<p>Warnings</p> <p>For external use only</p> <p>Do not use if you are allergic to any of the ingredients</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ serious burns ■ deep or puncture wounds ■ animal bites <p>When using this product</p> <ul style="list-style-type: none"> ■ do not use in the eyes ■ do not apply over large areas of the body <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ you need to use more 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 	<p>Other information ■ store at 59° to 77°F</p>
	<p>Inactive ingredients Liquid paraffin, Cethanol, Squalane, Lanolin, Petrolatum, Tocopheryl acetate</p>
	<p><small>*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Original Neosporin.®</small></p>

Made in Korea

SOOTHING OINTMENT



SOOTHING OINTMENT *Original*

TRIPLE ANTIBIOTIC

Polymyxin B Sulfate-Bacitracin Zinc-Neomycin Sulfate

NET 1 oz (28.3g)

Active ingredients (in each gram)

Bacitracin Zinc 400 units, Neomycin 3.5mg, Polymyxin B Sulfate 5,000 units

Uses First aid to help prevent infection and provide 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.

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. ■ May be covered with a sterile bandage.

- Children under 2 years of age: Consult a physician.

Other information ■ Store at 20° to 25°C (68° to 77°F)

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TRIPLE ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53210-1004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 U 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 U in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
SQUALANE (UNII: GW89575KF9)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53210-1004-0	1 in 1 BOX		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/26/2012	

Labeler - Morales Distributors Inc. (127151731)