

ANTIBIOTIC - neomycin 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.

Antibiotic Ointment

Active ingredients (in each gram)

Neomycin Sulfate 3.5mg

Purpose

First aid antibiotic

Uses

First aid to help prevent infection in minor:

- cuts
- scrapes
- 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 ingredients
- longer than one week unless directed by a doctor

Consult a doctor in case of

- deep or puncture 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

in case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

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 room temperature

Inactive ingredients

Liquid paraffin, Cethanol, Squalane, Purified lanolin, White petrolatum, Cetearyl alcohol, Tocopheryl acetate, Methylparaben, Propylparaben

Package label

NDC NO. 53210-1003-0

Compare to Vitacilinia First Aid Antibiotic active ingredient

MAXIMUM STRENGTH

ANTIBIOTIC OINTMENT

Neomycin Sulfate

FIRST AID ANTIBIOTIC OINTMENT

Net 1 oz (28.3g)

Exclusively distributed by:

Morales Distributors, Inc.

Mayaguez, P.R. 00682

Made in Korea



NDC NO. 53210-1003-0

Compare to
VITACILINA First Aid
Antibiotic active ingredient*



Maximum Strength

ANTIBIOTIC OINTMENT

Neomycin Sulfate

FIRST AID ANTIBIOTIC OINTMENT

**Maximum Strength
ANTIBIOTIC OINTMENT**

LOT & EXP.

FIRST AID ANTIBIOTIC OINTMENT

ANTIBIOTIC OINTMENT

NET 1 oz(28.3g)

MAXIMUM STRENGTH
ANTIBIOTIC OINTMENT
FIRST AID ANTIBIOTIC OINTMENT



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



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ANTIBIOTIC OINTMENT

Drug Facts

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■ cuts ■ scrapes ■ burns

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Drug Facts (continued)

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*This product is not manufactured or distributed by VITACILINA Corporation, owner of the registered trademark VITACILINA.

Made in Korea

Maximum Strength



FIRST AID ANTIBIOTIC OINTMENT
ANTIBIOTIC OINTMENT

NET 1 oz (28.3g)

Active ingredients (in each gram) Neomycin Sulfate 3.5mg Neomycin

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ANTIBIOTIC

neomycin sulfate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53210-1003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
SQUALANE (UNII: GW89575KF9)	

LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53210-1003-0	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	09/25/2012	

Labeler - Morales Distributors Inc (127151731)

Revised: 9/2012

Morales Distributors Inc