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

ANTIBIOTIC OINTMENT

NET 1 oz(28.3g)



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







Drug Facts

Active ingredient (in each gram) Neomycin Sulfate 3.5mg First aid antibiotic

Purpose

Uses First aid to help prevent infection in minor:

a cuts a scrapes a burns

Warnings

For external use only

Do not use

- m 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
- m serious bums

Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops

Drug Facts(continued)

Keep out of the 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

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

Made In Korea

Maximum Strength





NET 1 oz (28.3g)

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

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

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

ANTIBIOTIC

neomycin sulfate ointment

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:53210-1003
Route of Administration	TOPICAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NEO MYCIN SULFATE (NEOMYCIN)	NEOMYCIN SULFATE	3.5 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
MINERAL OIL	
SQUALANE	

LANOLIN	
PETROLATUM	
CETOSTEARYL ALCOHOL	
.ALPHATO COPHEROL ACETATE	
METHYLPARABEN	
PROPYLPARABEN	

P	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	

$\boldsymbol{Labeler} \text{ - Morales Distributors Inc (127151731)}$

Revised: 9/2012 Morales Distributors Inc