

## **ANTIBIOTIC OINTMENT - neomycin sulfate ointment**

**NeoPharm Co., Ltd.**

*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.*

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### **Drug Facts**

#### **Active ingredient (in each gram)**

Neomycin Sulfate 3.5mg

#### **Purposes**

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**

Antibiotic Ointment

Maximum Strength  
ANTIBIOTIC OINTMENT

NDC No. 68374-066-04

Pure-Aid™

Compare to  
VITACILINA® First Aid  
Antibiotic active ingredient\*

# ANTIBIOTIC OINTMENT

Neomycin Sulfate  
FIRST AID ANTIBIOTIC OINTMENT



## KAREWAY

■ MAXIMUM STRENGTH ■

# ANTIBIOTIC OINTMENT

Neomycin Sulfate  
FIRST AID ANTIBIOTIC OINTMENT  
NET 1oz(28.3g)

MAXIMUM STRENGTH  
ANTIBIOTIC  
OINTMENT

# ANTIBIOTIC OINTMENT

Neomycin Sulfate  
FIRST AID ANTIBIOTIC OINTMENT



LOT & EXP.

Made in Korea

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

**Inactive ingredients**  
Liquid petrolatum, Cetanol, Squelane, Purified lanolin, White petrolatum, Cetearyl alcohol, Tocopheryl acetate, Methylparaben, Propylparaben

**Other information** ■ store at room temperature

**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

**Keep out of the reach of children**  
In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**Drug Facts (continued)**



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■ cuts ■ scrapes ■ burns  
**Warnings**  
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■ 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**  
■ a rash or other allergic reaction develops  
■ the condition persists or gets worse

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51141-0066
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
SQUALANE (UNII: GW89575KF9)	
LANOLIN (UNII: 7EV65EAW6H)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
METHYLPARABEN (UNII: A218C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51141-0066-1	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	08/26/2010	

**Labeler** - NeoPharm Co., Ltd. (631101883)

**Registrant** - NeoPharm Co., Ltd. (631101883)

### Establishment

Name	Address	ID/FEI	Business Operations
NeoPharm Co., Ltd.		631101883	manufacture

Revised: 8/2010

NeoPharm Co., Ltd.