# ANTIBIOTIC- neomycin sulfate ointment Promex, LLC

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 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 woundsanimal bitesserious burns

#### Stop use and ask a doctor if

the condition persists or gets worsea rash or other allergic reaction occurs

#### 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 finer) 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

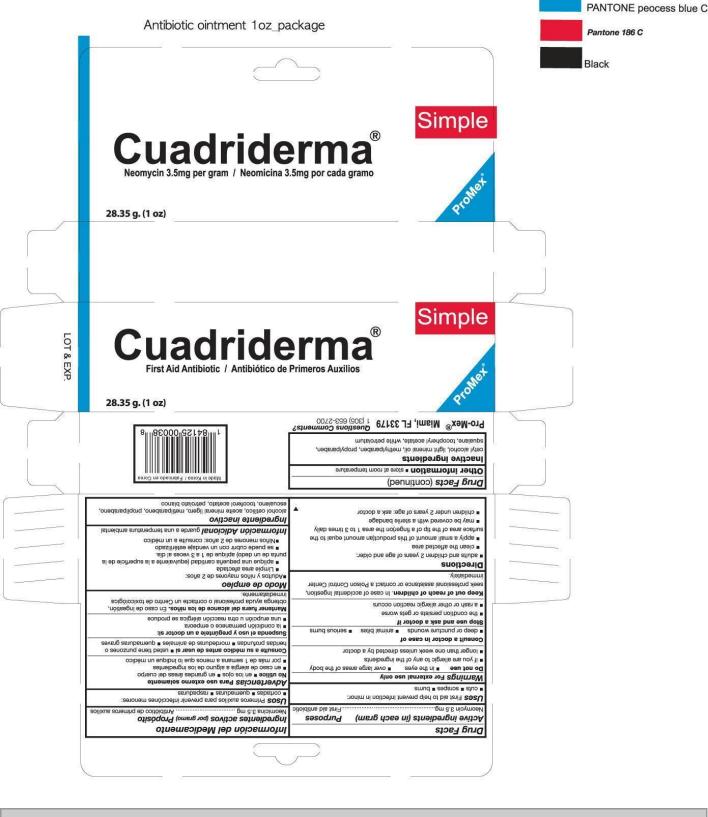
• store at room temperature

## **Inactive ingredients**

Cetyl alcohol, Light Mineral Oil, Methylparaben, Propylparaben, Squalane, Tocopheryl acetate, White petrolatum

## Package label

Antibiotic Ointment



#### **ANTIBIOTIC**

neomycin sulfate ointment

<b>Product Information</b>	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58988-0038		
Route of Administration	TOPICAL				

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

Inactive Ingredients		
Ingredient Name	Strength	
CETYL ALCOHOL (UNII: 936JST6JCN)		
SQUALANE (UNII: GW89575KF9)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
PETROLATUM (UNII: 4T6 H12BN9 U)		
.ALPHATO COPHERO L ACETATE, D- (UNII: A7E6112E4N)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:58988-0038-1	1 in 1 BOX				
1		28.35 g in 1 TUBE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333B	12/05/2013		

## **Labeler -** Promex, LLC (789974388)

Revised: 12/2013 Promex, LLC