

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.

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 wounds animal bites serious burns

Stop use and ask a doctor if

the condition persists or gets worse a 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 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

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

Package label

Antibiotic Ointment

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	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: 4T6H12BN9U)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

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)

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