

POMADA SULFA FIRST AID ANTIBIOTIC- neomycin sulfate gel
Grandall Distributing Co., 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.

POMADA SULFA FIRST AID ANTIBIOTIC

ACTIVE INGREDIENT

Neomycin Sulfate 5 mg (equivalent to 3.5 mg of Neomycin)

PURPOSE

ANTIBIOTIC

INDICATIONS

First aid to help prevent infection in minor cuts, scrapes and burns.

WARNINGS

For external use only. Do not use in the eyes or over large areas of the body. In case of deep or puncture wounds, animal bites or serious burns, consult a doctor. Stop use and consult a doctor if condition persists or gets worse. Do not use longer than one week unless directed by a doctor. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Store at room temperature.

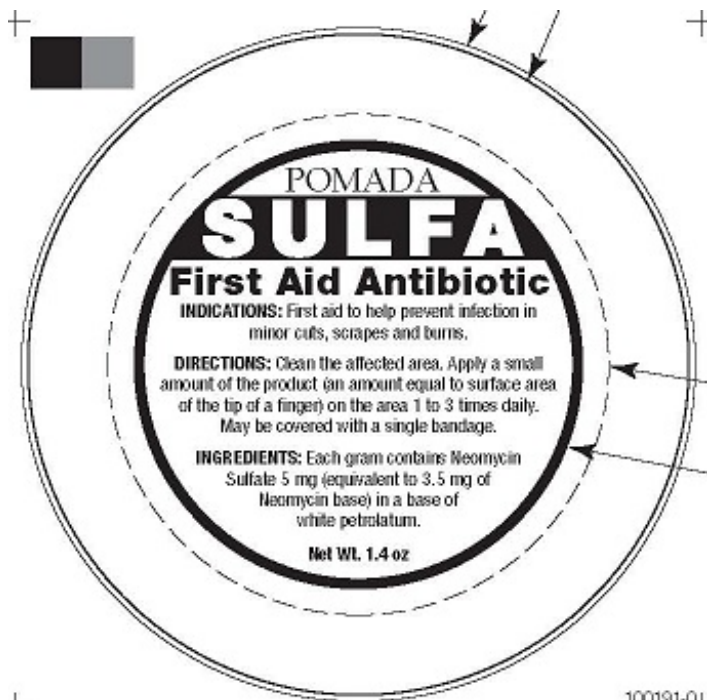
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

DIRECTIONS

Clean the affected area. Apply a small amount of the product (an amount equal to surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a single bandage.

INACTIVE INGREDIENTS

WHITE PETROLATUM



POMADA SULFA FIRST AID ANTIBIOTIC

neomycin sulfate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48 201-10 1
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	5 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48201-101-11	40 g in 1 JAR; Type 0: Not a Combination Product	02/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	02/06/2020	

Labeler - Grandall Distributing Co., Inc. (044428324)**Establishment**

Name	Address	ID/FEI	Business Operations
HealthSpecialty		794053863	manufacture(48201-101)

Revised: 2/2020

Grandall Distributing Co., Inc.