TRIPLE ANTIOBIOTIC- triple antibiotic ointment ointment Davemed Healthcare 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.

Triple Antiobiotic

DIRECTIONS

- clean affected area
- apply small amount not more than 3 times daily
- maybe covered with a sterile bandage
- children under 2 years of age ask a doctor

USES

First aid to help prevent infection and for the temporary relief of pain and itching associated with minor cuts, scrapes and burns

FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

If ingested contact a poison control center right away.

NEOMYCIN

BACITRACIN

PRAMOXINE HCI

Petrolatum

First Aid Antibiotic. For temporary relief of pain associated with minor burns.

B209

Triple Antibiotic Ointment

EACH GRAM CONTAINS:

Neomycin Sulfate Equivalent to 3.5mg (Neomycin base)

> NET WT 0.9g (1/32 OZ) NDC#

For temporary Relief of Pain Associated with Minor Burns

Drug Facts

Active Ingredients (in each gram)

Neomycin 3.5mg — First aid antibiotic
Bacitracin 500 units — First aid antibiotic
Pramoxine HCI 10mg — External analgestic

Uses: First aid to help prevent infection and for the temporary relief of pain and itching associated with minor cuts • scrapes • burns

Warnings: For external use only

Do not use • in eyes • in large quantities • over raw blistered areas, or on deep puncture wounds, animal bites or serious burns • for more than one week

Keep out of reach of Children If ingested, contact a Poison Control Center right away.

Directions: • clean affected area • apply small amount not more than 3 times daily • Maybe covered with a sterile bandage • Children under 2 years of age: ask a doctor

Orther Inforamtion: store at room temperature

Manufactured in China for Davemed Healthcare Co., Ltd

TRIPLE ANTIOBIOTIC

triple antibiotic ointment ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70897-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN	5 mg in 1 g
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO 52I)	BACITRACIN	400 [iU] in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-003-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product	08/11/2016	
2	NDC:70897-003-02	14.2 g in 1 TUBE; Type 0: Not a Combination Product	08/11/2016	
3	NDC:70897-003-03	28.4 g in 1 TUBE; Type 0: Not a Combination Product	08/11/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333B	08/11/2016		

Labeler - Davemed Healthcare Co., Ltd. (529128716)

Establishment				
Name	Address	ID/FEI	Business Operations	
Davemed Healthcare Co., Ltd.		529128716	manufacture(70897-003)	

Revised: 2/2019 Davemed Healthcare Co., Ltd.