

TRIPLE ANTIBIOTIC- triple antibiotic ointment
ProStat First Aid

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.

2009 Triple Antibiotic

Active Ingredient (in each gram)

Bacitracin Zinc 400 Units

Active Ingredient

Neomycin Sulfate 5mg (Equivalent to 3.5 mg Neomyxin)

Active Ingredient (in each gram)

Polymyxin B Sulfate 5000 Units

Purpose

First Aid Antibiotic

Use(s)

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

Warnings

For External Use Only

Do not use

- In the eyes or apply over large areas of the body
- If you are allergic to any of the ingredients
- Longer than 1 week unless directed by a doctor

Ask a doctor before use if

you have deep or puncture wounds, animal bites, or 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

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Clean the affected area. Apply a small amount of the 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.

Other Information

- Store at room temperature between 15°-30°C (59°-86°F)
- Tamper evident. Do not use if packet is torn, cut, or opened.

Inactive Ingredient

White Petrolatum

Questions?

1-888-900-2920 Monday - Friday 8AM - 4PM PST

Label



Triple Antibiotic Ointment

TRIPLE ANTIBIOTIC

triple antibiotic ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58228-2009
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 1 g
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Product Characteristics

Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58228-2009-2	1800 in 1 CASE	04/10/2023	
1	NDC:58228-2009-1	25 in 1 BOX		
1		0.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/10/2023	

Labeler - ProStat First Aid (061263699)

Revised: 3/2023

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