

**TRIPLE ANTIBIOTIC - bacitracin zinc and neomycin and polymyxin b sulfate ointment  
Melaleuca, 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.*

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**Triple Antibiotic Ointment Label**

**Active Ingredients** (each gram contains:)

Bacitracin zinc 500 units

Neomycin 3.5 mg

Polymyxin B sulfate 10,000 units

**Purpose**

antibiotic

**Uses**

First aid to help prevent the risk of 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

**Ask a doctor**

**before use** in case of 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

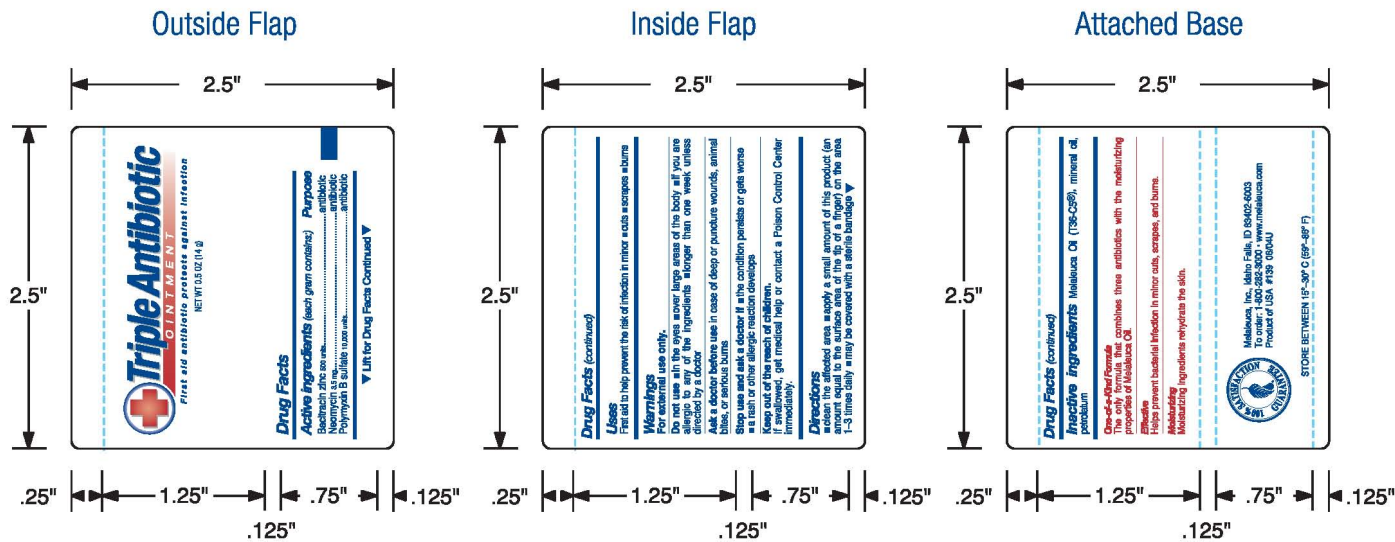
**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**

- 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 1-3 times daily
- may be covered with a sterile bandage

Inactive ingredients: Melaleuca Oil (T36-C5<sup>(R)</sup>), mineral oil, petrolatum



## TRIPLE ANTIBIOTIC

bacitracin zinc and neomycin and polymyxin b sulfate ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-578
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN ZINC - UNII:89 Y4M234ES)	BACITRACIN ZINC	500 [iU] in 1 g
NEOMYCIN (UNII: I16 QD7X297) (NEOMYCIN - UNII:I16 QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B SULFATE	10000 [iU] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Tea Tree Oil (UNII: VIF565UC2G)	
MINERAL OIL (UNII: T5L8T28FGP)	

**Petrolatum** (UNII: 4T6H12BN9U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-578-01	14 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	07/01/1995	

**Labeler** - Melaleuca, Inc. (139760102)

### Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		139760102	manufacture

Revised: 12/2010

Melaleuca, Inc.