

**BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE- bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment  
Kinray 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.*

-----

**Triple Antibiotic Ointment**

**Active ingredient (in ea. gram)**

Bacitracin Zinc 400 Units

Neomycin Sulfate 5mg (Equivalent to 3.5 mg Neomycin)

Polymyxin B Sulfate 5000 Units

**Purpose**

First Aid Antibiotic

First Aid Antibiotic

First Aid Antibiotic

**Warnings:**

For external use only

**Dosage and Administration**

- clean the affected areas
- apply a small amount of product (an amount equal to the surface area of the tip of the finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

**Stop use and ask a doctor if**

- the condition persists or gets worse, or if a rash or other allergic reaction develops.

**Indications and Usage**

- if you are allergic to any of the ingredients
- in the eyes
- over large areas of the body
- longer than 1 week unless directed by a doctor

**Keep out of reach of children**

if swallowed, get medical help or contact a Poison Control Center right away

**Purpose**

First aid to help prevent infection in:

Minor cuts

scrapes

burns

**Ask a doctor before use:**

- in case of deep or puncture wounds
- animal bites
- serious burns

## Other information

- store at controlled room temperature 15°-30° C (59°-86° F)
- avoid excessive heat and humidity

## Inactive ingredients:

Hard Paraffin, Liquid Paraffin, White Soft Paraffin

## Principal Display Panel

Triple Antibiotic Ointment:

triple\_antibiotic.jpg



## BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE

bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63777-217
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6RWO52I)	BACITRACIN	400 [iU] in 1 g

NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	5000 [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:63777-217-01	28.35 g in 1 TUBE		
2	NDC:63777-217-02	14.17 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/15/2010	

**Labeler** - Kinray Inc. (012574513)

**Registrant** - Dynarex Corporation (008124539)

### Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma India Private Limited		918531450	manufacture(63777-217)

Revised: 1/2014

Kinray Inc.