

BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE- bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment
Galentic Pharma (India) Private Limited

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.

Galentic 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

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Purpose:

First aid to help prevent infection in:

- Minor cuts
- scrapes
- burns

Indications and Usage:

- 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

Keep Out Of Reach Of Children

KEEP OUT OF REACH OF CHILDREN

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

Do Not Use:

- 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

Stop use and ask a doctor if

- Stop use and ask a doctor if condition persists or gets worse, or if a rash or other allergic reaction occurs

Principal Display Panel

Galentic Triple Antibiotic Ointment

Gal Triple.jpg



BACITRACIN ZINC, NEOMYCIN SULFATE AND POLYMYXIN B SULFATE			
bacitracin zinc, neomycin sulfate and polymyxin b sulfate ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-008
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN	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:50382-008-01	28.35 g in 1 TUBE		
2	NDC:50382-008-02	14.17 g in 1 TUBE		
3	NDC:50382-008-03	56.7 g in 1 TUBE		
4	NDC:50382-008-04	113.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/07/2013	

Labeler - Galentic Pharma (India) Private Limited (918531450)

Revised: 8/2013

Galentic Pharma (India) Private Limited