

ANCALIMA BACITRACIN ZINC FIRST AID- bacitracin zinc ointment
ANCALIMA LIFESCIENCES 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.

ANCALIMA Bacitracin Zinc

Active Ingredient (in each gram)

Bacitracin Zinc (equal to 500 bacitracin units)

Purpose

First Aid Antibiotic

Uses

■ first aid to help prevent infection in minor ■ cuts ■ scrapes ■ burns

Warnings

For external use only

Do not use

■ Not for ophthalmic use **Do not use** ■ in the eyes ■ if you are allergic to any of the ingredients ■ over large areas of the body longer than 1 week unless directed by a doctor

Ask a doctor before use in case of

■ deep or puncture wounds
■ animal bites ■ 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 to 3 times daily •may be covered with a sterile bandage

Other Information

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

Inactive Ingredients

hard paraffin, liquid paraffin, white soft paraffin, lanolin

Package Label



ANCALIMA BACITRACIN ZINC FIRST AID

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:730 14-30 35
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6RWO52I)	BACITRACIN	500 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
PARAFFIN (UNII: I9O0E3H2ZE)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73014-3035-2	0.9 g in 1 PACKET; Type 0: Not a Combination Product	04/08/2019	
2	NDC:73014-3035-3	14 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	
3	NDC:73014-3035-4	28 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	
4	NDC:73014-3035-5	113 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	
5	NDC:73014-3035-6	425 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	04/08/2019	

Labeler - ANCALIMA LIFESCIENCES LIMITED (676760093)

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