

BUDPAK BACITRACIN- bacitracin zinc ointment

Budpak 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.

Budpak Bacitracin Ointment

Active Ingredient (each gram contains):

Bacitracin Zinc 500 units

Purpose:

First aid antibiotic

Uses:

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

Warnings:

For external use only.

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 or serious burns

Stop use and ask a doctor if:

Condition persists or gets worse. 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 to 3 times daily may be covered with a sterile bandage.

Other Information:

Store at 15°C to 25°C (59°F to 77°F). Lot No. & Exp. Date: See box or crimp of tube.

Inactive Ingredients:

Hard Paraffin, Liquid Paraffin, White Soft Paraffin .

PRINCIPAL DISPLAY PANEL

Budpak Bacitracin Ointment

First Aid Antibiotic with Zinc

NET WT .5 OZ (14 g)

Budpak

compare to the active ingredients in
National Brands

Bacitracin Ointment

FIRST AID ANTIBIOTIC

With Zinc

Helps Prevent Infection In Cuts, Scrapes & Burns

Bacitracina Ungüento

Con antibiótico y zinc

compare con ingrediente activo en
Marcas Nacionales

Ayuda a prevenir la infección en heridas menores, raspaduras y quemaduras

Bacitracin Ointment

FIRST AID ANTIBIOTIC

compare to the active ingredients in
National Brands

With Zinc

Helps Prevent Infection In Cuts, Scrapes & Burns

NET WT
.5 OZ (14g)



Manufactured in India.
Distributed by Budpak, Inc.
100 North Drive
Ronkonkoma, NY 11779
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Bacitracin Ointment

FIRST AID ANTIBIOTIC

With Zinc

Budpak

Bacitracin Ointment
FIRST AID ANTIBIOTIC
With Zinc

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FIRST AID ANTIBIOTIC
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Drug Facts

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Bacitracin Ointment
FIRST AID ANTIBIOTIC
With Zinc

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BUDPAK BACITRACIN

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-035	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)		BACITRACIN	500 [iU] in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
MINERAL OIL (UNII: T5L8T28FGP)				
PARAFFIN (UNII: I9O0E3H2ZE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-035-14	14 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333B	03/30/2015		

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-035)

Revised: 3/2015

Budpak Inc.