BACITRACIN ZINC- bacitracin zinc ointment Aidarex Pharmaceuticals LLC

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.

Bacitracin Zinc Ointment, USP

ACTIVE INGREDIENT

(in each gram)

Bacitracin zinc, USP 500 units

PURPOSE

First aid antibiotic

USES

Helps prevent infection in

- minor cuts
- scrapes
- burns

WARNINGS

For external use only

Allergy alert:

do not use if allergic to any of the ingredients

DO NOT USE

- in the eyes
- over large areas of the body

ASK A DOCTOR BEFORE USE IF YOU HAVE

- deep or puncture wounds
- animal bites
- serious burns

WHEN USING THIS PRODUCT

• do not use longer than 1 week unless directed by a doctor

STOP USE AND ASK A DOCTOR IF

- 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 right away.

DIRECTIONS

- clean affected area
- apply a small 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 59°-77°F (15°-25°C).

INACTIVE INGREDIENT

White petrolatum

QUESTIONS?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Repackaged By:

Aidarex Pharmaceuticals, LLC

Corona, CA 92880

NDC 33261-707-01

Bacitracin Zinc Ointment, USP

First Aid Antibiotic Ointment

Net WT 1 OZ (28 g)

11051210E1 VC110188



Image Label

BACITRACIN ZINC bacitracin zinc ointment Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-707(NDC:0472-1105)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89 Y4M234ES) (BACITRACIN - UNII:58 H6 RWO52I)	BACITRACIN ZINC	500 [USP'U] in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6 H12BN9 U)	

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:33261-707-56	1 in 1 CARTON				
1	NDC:33261-707-01	28 g in 1 TUBE				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333B	03/01/2002		

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 9/2012 Aidarex Pharmaceuticals LLC