BACITRACIN- bacitracin 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.

Bacitracin Ointment

Active ingredient Purpose Bacitracin Zinc 500 Units Antibiotic

Purpose:

First aid to help prevent infection.

Warnings:

For external use only

Dosage and Administration

Directions:

- clean the affected areas
- apply a small amount of product (an amountb 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

Indications and Usage

First aid to help prevent infection in:

- minor cuts
- scrapes
- burns

Stop Use and ask a doctor if:

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

Do Not Use if:

- 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

Ask a doctor before use:

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

Keep out of reach of children

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

Other information

• store at controlled room temperature 15°-30° C (59°-86° F)

Inactive ingredients

Light Mineral Oil, White Petrolatum

Principal Display Panel

Kinray Bacitracin Ointment:

KR1163 Bacitracin.jpg

BACITRACIN (OINTMENT, USP

NDC # 61715-079-01

For minor cuts, burns and scrapes
COMPARE & SAVE

NET WT. 1 oz. (28.4 g)

Drug Facts

Active IngredientPurpose

Bacitracin Zinc (Equal to 500 Bacitracin Units) First Aid Antibiotic

Uses • First aid to help prevent infection in • Minor cuts • Scrapes • 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 • 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. 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°-30° C (59°-86° F)

Inactive Ingredients • Liquid Paraffin, White Soft Paraffin, Hard Paraffin

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BACITRACIN

bacitracin ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61715-079

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	BACITRACIN (UNII: 58 H6 RWO52I) (BACITRACIN - UNII:58 H6 RWO52I)	BACITRACIN	500 [iU] in 1 g

Inactive Ingredients

Ingredient Name	Strength

MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

l	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 NDC:61715-079-01	28.35 g in 1 TUBE				

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	08/02/2013	

Labeler - Kinray Inc. (012574513)

Registrant - Dynarex Corporation (008124539)

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