

BACITRACIN- bacitracin zinc ointment
Trifecta Pharmaceuticals USA, 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

Bacitracin Zinc 500 Units per gram

Purpose

First Aid Antibiotic

Uses

First Aid to help prevent infection in

- minor cuts
- scrapes
- burns

Warnings

For External Use Only.

Do not use; in eyes, over large areas of the body, if you are allergic to any of the ingredients, longer than 1 week unless directed by a doctor.

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Stop Use and Ask Doctor if

- The condition persists or gets worse
- A rash or allergic reaction develops

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

Inactive Ingredients

Aloe vera gel, light mineral oil, white petrolatum

Other Information

Store between 15° to 25°C (59° to 77°F)

Lot No and Expiration Dates - please see box and tube crimp

100% GUARANTEED

Distributed By:

Trifecta Pharmaceuticals USA ®

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

Ask

OUTSIDE BOX





INNER TUBE



BACITRACIN

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-027-01	1 in 1 BOX	03/15/2017	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

OUTER BOX



INNER TUBE



covered with a sterile bandage. **Other information** ■ store between 15° to 25° C (59° to 77°F) ■ Lot No. & Expiration Date: See box and tube crimp. **Questions?** Call 1-888-296-6067 **inactive ingredients:** aloe oil, light mineral oil, white petrolatum
Distributed by: Trifecta Pharmaceuticals USA®
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	03/15/2017	

Labeler - Trifecta Pharmaceuticals USA, LLC. (079424163)

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Trifecta Pharmaceuticals USA, LLC.