BACITRACIN ZINC- bacitracin zinc ointment
GERITREX 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 USP Ointment

Active Ingredient: **Purpose:**

Bacitracin Zinc 500 units (each gram).....First Aid Antibiotic

Uses:

Helps prevent infection in: Minor cuts, scrapes, and/or burns

Warnings:

FOR EXTERNAL USE ONLY
Allergy Alert: Do not use if allergic to any of the ingredients.
Do not use in eyes or on large areas of the body.
Ask a doctor before use if you have deep or puncture wounds, animal bites or 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 lasts or gets worse, rahs or other allergic reaction develops.

KEEP OUT OF REACH OF CHILDREN
In the event of accidental ingestion, contact a Poison Control Center right away.

Directions:

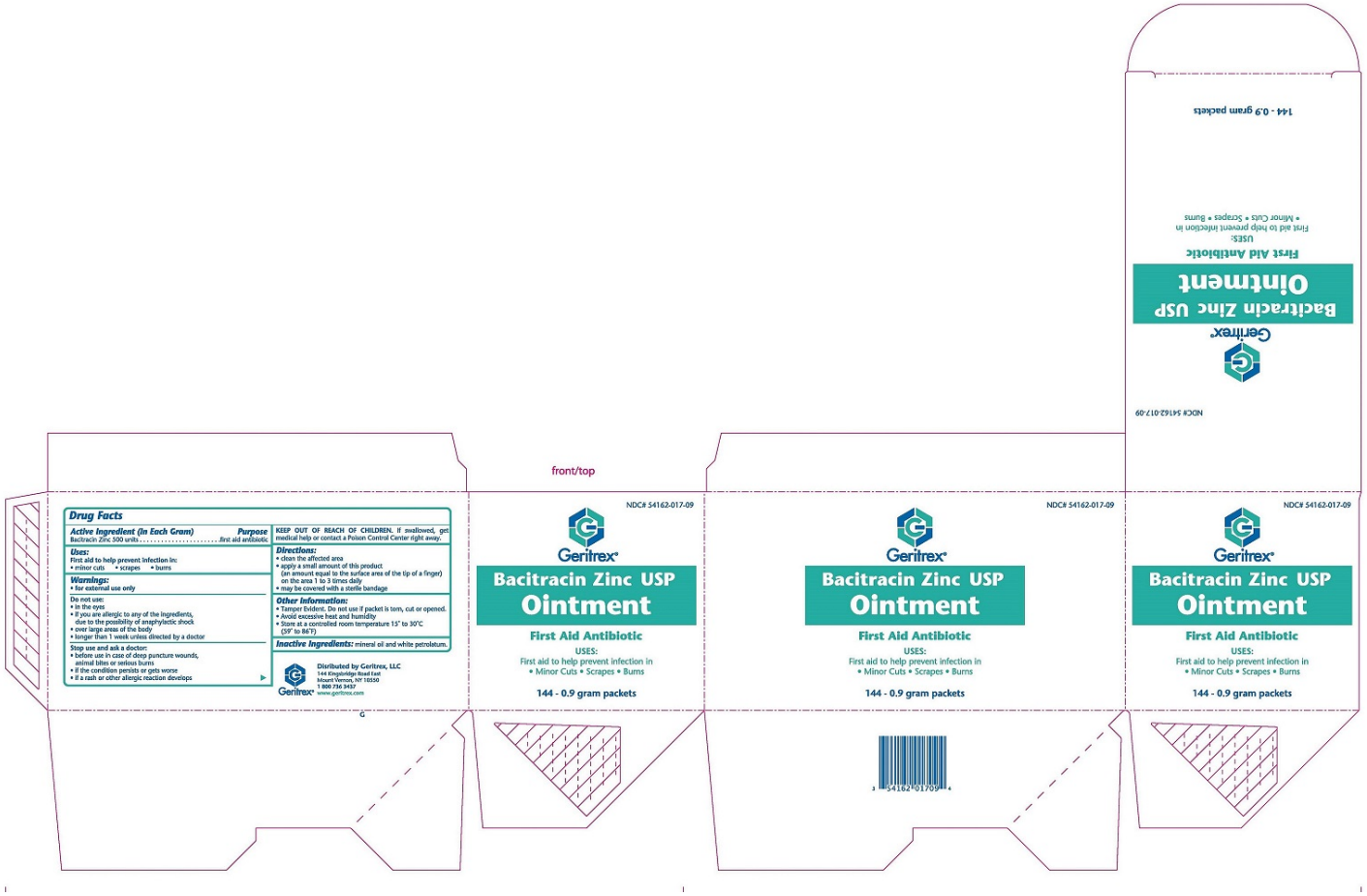
Clean affected area. Apply a small amount (equal to surface area of tip of finger) on area 1 to 3 times daily. May be covered with a sterile bandage.

Inactive Ingredients:

Mineral Oil and White Petrolatum

Other Information:

Store at controlled room temperature
59°-86°F (15°-30°C).


front/top
Drug Facts
Active Ingredient (In Each Gram) Purpose
Bacitracin Zinc 500 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, due to the possibility of anaphylactic shock
• over large areas of the body
• longer than 1 week unless directed by a doctor
Stop use and ask a doctor:
• before use in case of deep puncture wounds, animal bites or serious burns
• if the condition persists or gets worse
• if 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:
• Tamper Evident. Do not use if packet is torn, cut or opened.
• Avoid excessive heat and humidity
• Store at a controlled room temperature 15° to 30°C (59° to 86°F)
Inactive Ingredients: mineral oil and white petrolatum.
Distributed by Geritrex, LLC
144 Kingsbridge Road East
Mount Vernon, NY 10550
1 800 736 3437
www.geritrex.com
NDC# 54162-017-09
Geritrex®
Bacitracin Zinc USP
Ointment
First Aid Antibiotic
USES:
First aid to help prevent infection in
• Minor Cuts • Scrapes • Burns
144 - 0.9 gram packets
NDC# 54162-017-09
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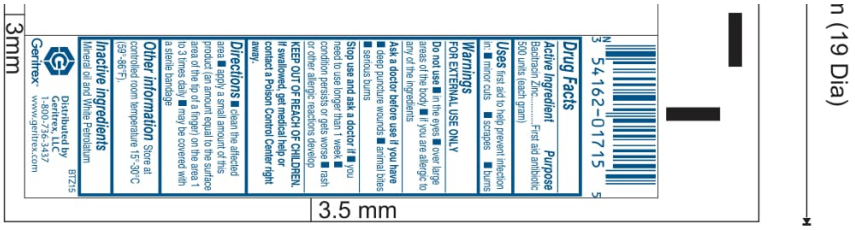
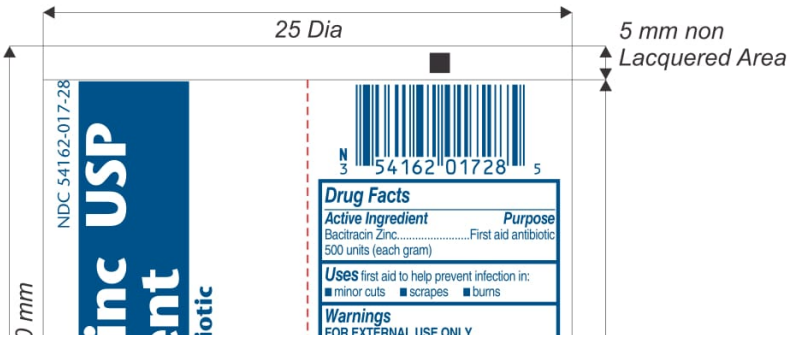
Tube Length 112mm (+/- 1mm)
4.5 mm
NDC 54162-017-15
Geritrex®
Bacitracin Zinc USP
Ointment
First Aid Antibiotic
NET WT. 0.5oz (15g)
15mm
61.5 mm



Key Line Drawing for Seamless Printed Tubes
Dia 25, Tube Length 125 mm
With Topseal and Screw on Cap
Orifice 4mm



BACITRACIN ZINC

bacitracin zinc ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-017
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)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-017-15	15 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-017-28	28 g in 1 TUBE; Type 0: Not a Combination Product	11/01/2017	
3	NDC:54162-017-09	0.9 g in 1 POUCH; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	05/15/2014	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-017)

Revised: 1/2018 GERITREX LLC