

MAJOR BACITRACIN ZINC- bacitracin zinc ointment

Major Pharmaceuticals

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.

Drug Facts

Active ingredients (In each gram)

Bacitracin 500

Purpose

First aid antibiotic

Uses

First aid to help prevent infection in minor:

- cuts
- scrapes
- burns

Warnings

For external use only

Allergy alert:

- do not use if you are allergic to any of the ingredients

Do not use

- in or near the eyes
- on large areas of the body

Consult 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

Stop use and consult a doctor if

- condition persists or gets worse
- symptoms last for more than 7 days or clear up and come back within a few days
- a rash or other allergic reaction develops

Keep out of the reach of children. If swallowed get medical help or contact a Poison Control Center immediately.

Directions

- clean the affected area
- apply a small amount (equal to surface area of tip of finger) on the area 1 to 3 times daily.
- may be covered with a sterile bandage

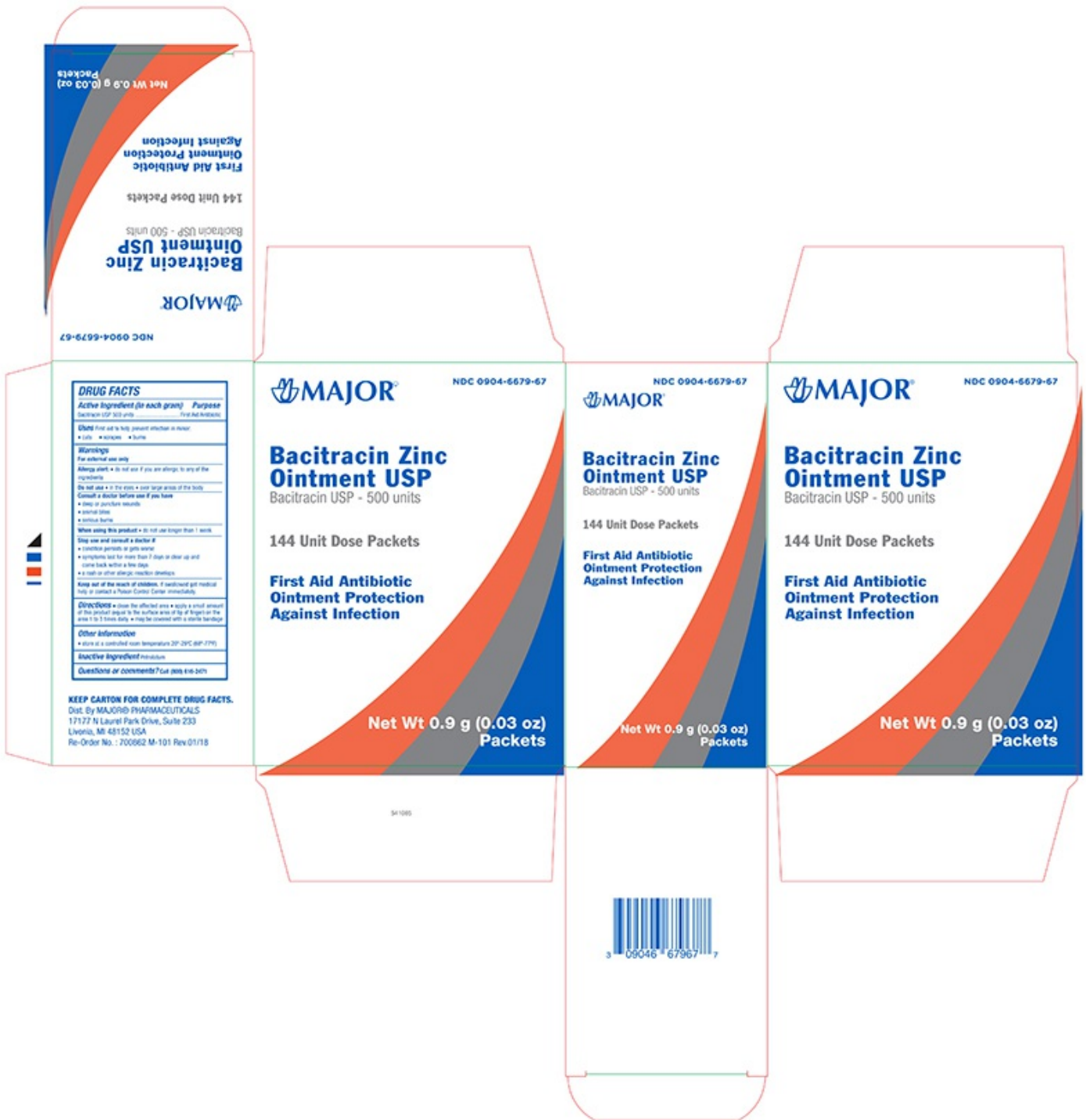
Other information

- Store at a controlled room temperature 20°-25°C (68° to 77°F)

Inactive ingredient

Petrolatum

Questions? 1-800-616-2471



Principal Display Panel – Carton Label

Major NDC 0904-6679-67

Bacitracin Zinc Ointment USP

Bacitracin Zinc 500 units

144 Unit dose Packets

First Aid Antibiotic Ointment

NET WT. 0.9g (0.03oz)

MAJOR
Bacitracin Zinc Ointment USP - 500 units
 144 Unit Dose Packets
First Aid Antibiotic Ointment Protection Against Infection
 Net Wt 0.9 g (0.03 oz) Packets
 NDC 0904-6679-67

DRUG FACTS
 Active ingredient (per each gram) Purpose
 Bacitracin USP 500 units First Aid Antibiotic
 (1) Use: For use on cuts, scrapes, burns, blisters, and other minor skin injuries.
 (2) Use: For use on cuts, scrapes, burns, blisters, and other minor skin injuries.
 (3) Use: For use on cuts, scrapes, burns, blisters, and other minor skin injuries.
Warnings
 For external use only.
 Allergy alert: Do not use if you are allergic to any of the ingredients.
 Do not use: In the eyes, on ear, nose, or on large areas of the body.
 Consult a doctor before use if you have:
 • deep or puncture wounds
 • severe pain
 • serious burns
 When using this product: Do not use longer than 1 week.
 Stop use and consult a doctor if:
 • condition persists or gets worse
 • symptoms last for more than 7 days or clear up and come back within a few days
 • a rash or other allergic reaction develops
Keep out of the 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 the product equal to the surface area of the leg or the area 1 to 3 times daily • may be covered with a sterile bandage.
Other information
 • store at a controlled room temperature 20°-25°C (68°-77°F)
Inactive ingredient petroleum
Questions or comments? Call 800-645-6263

KEEP CARTON FOR COMPLETE DRUG FACTS.
 Dist. By MAJOR® PHARMACEUTICALS
 17177 N Laurel Park Drive, Suite 230
 Livonia, MI 48152 USA
 Re-Order No.: 700862 M-101 Rev 01/18

MAJOR® NDC 0904-6679-67

Bacitracin Zinc Ointment USP
 Bacitracin USP - 500 units

144 Unit Dose Packets

First Aid Antibiotic Ointment Protection Against Infection

Net Wt 0.9 g (0.03 oz) Packets

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M-101 Rev. 01/18

103105

Principal Display Panel – Packet Label

Major NDC 0904-6679-67

Bacitracin Zinc Ointment

Bacitracin Zinc 500 Units

144 Unit Dose Packets

First Aid Antibiotic Ointment

Protection against Infection

NET WT. 0.9g (0.03oz)

NDC 0904-6679-67



Bacitracin Zinc Ointment USP

Bacitracin USP - 500 units

First Aid Antibiotic Ointment Protection Against Infection

Net Wt 0.9 g (0.03 oz)

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MAJOR BACITRACIN ZINC

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6679
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Bacitracin Zinc (UNII: 89Y4M234ES) (Bacitracin - UNII:58H6RWO52I)	Bacitracin	500 [USPU] in 1 g

Inactive Ingredients

Ingredient Name	Strength
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Petrolatum (UNII: 4T6H12BN9U)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6679-67	144 in 1 CARTON	09/28/2018	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/28/2018	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(0904-6679)

Revised: 10/2018

Major Pharmaceuticals