

BACITRACIN- bacitracin zinc cream **HART Health**

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 Ingredients (in each gram):

Bacitracin zinc 500 units

Purpose:

Topical Antibiotic

Uses: First aid to help prevent infection in

- minor cuts
- scrapes
- burns
- abrasions

Warnings: For external use only

- do not get in eyes
- serious burns require immediate attention

Allergy alert: do not use if you are allergic to any of the ingredients

Do not use:

- in or near the eyes
- over large portions of the body
- more than 1 to 3 times daily
- longer than 7 days unless directed by a doctor

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens or lasts for more than 7 days
- a rash or other allergic reaction occurs

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away. 1-800-222-1222.

Directions: do not use more than directed

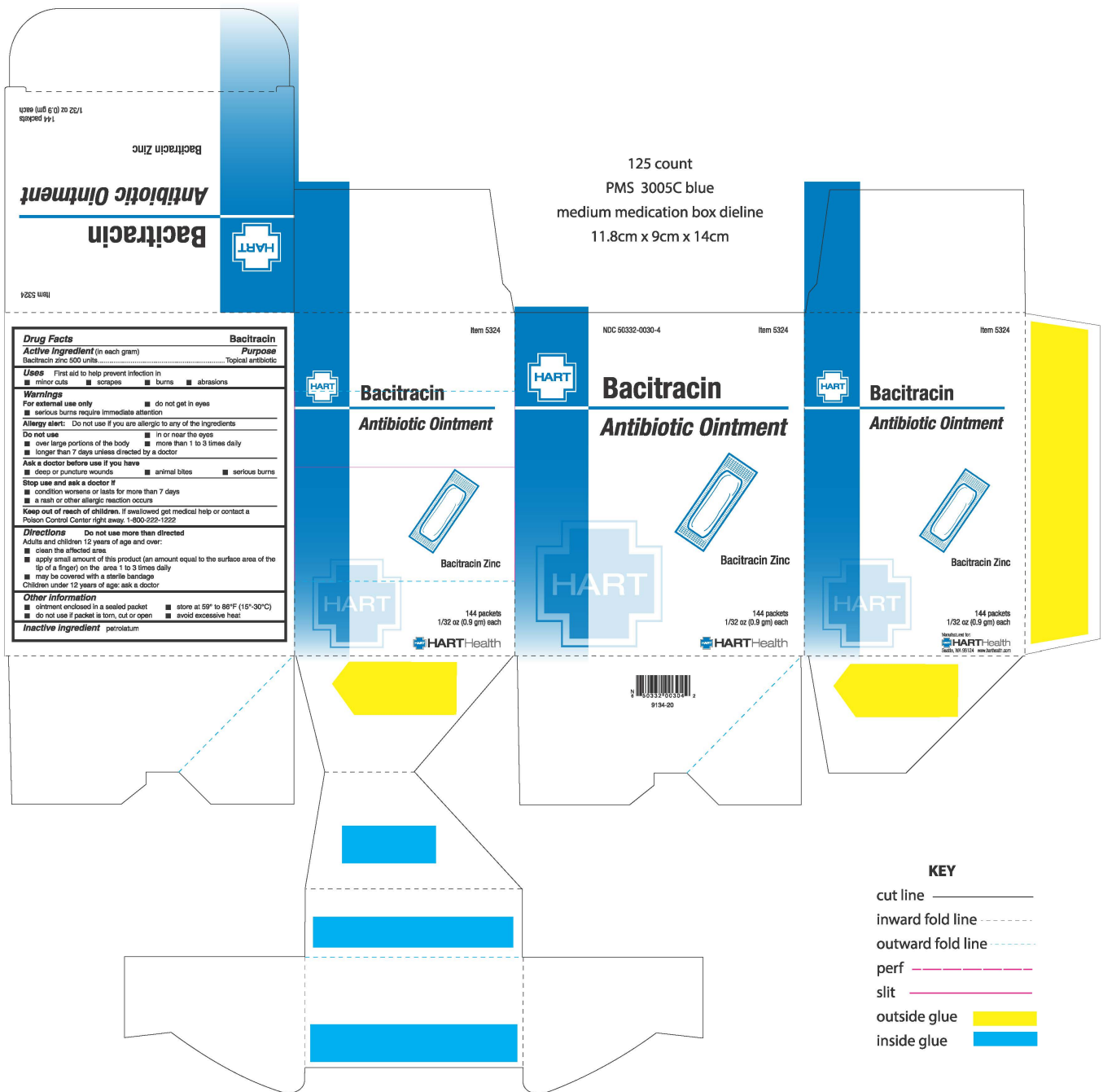
Adults and children 12 years of age and over:

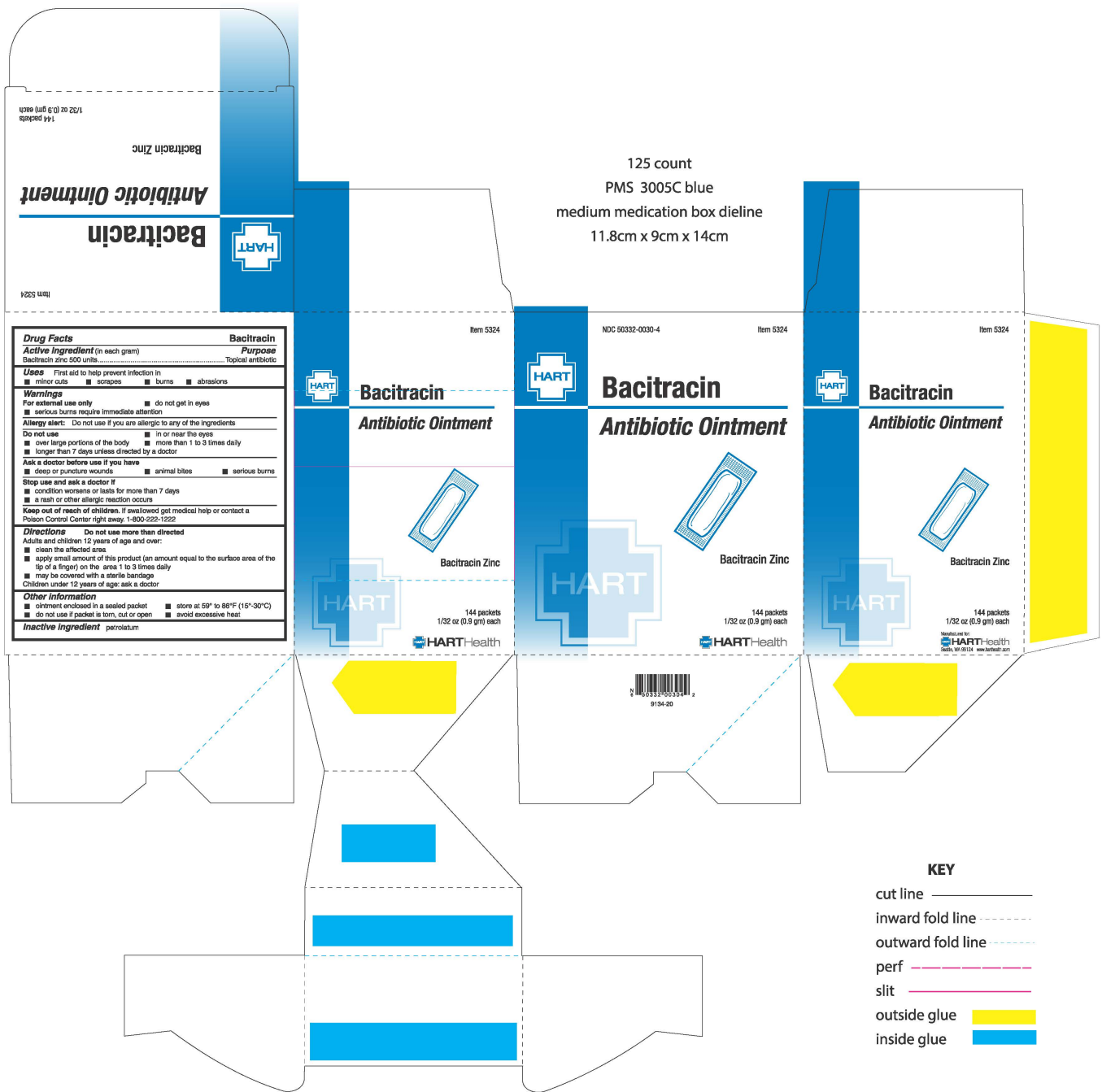
- clean the affected area
- apply small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily

- may be covered with a sterile bandage

Children under 12 years of age: ask a doctor

Inactive Ingredients: petrolatum





BACITRACIN

bacitracin zinc cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN ZINC	500 U in 0.9 g
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Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0030-4	144 in 1 BOX, UNIT-DOSE	01/05/2021	
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	01/05/2021	

Labeler - HART Health (069560969)

Registrant - HART Health (069560969)

Establishment

Name	Address	ID/FEI	Business Operations
WaterJel Technologies		155522589	manufacture(50332-0030)

Revised: 11/2022

HART Health