

SINGLE ANTIBIOTIC WITH BACITRACIN- bacitracin zinc ointment
Safetec of America

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 Ingredient (in each gram)

Bacitracin zinc (500 units bacitracin)

Purpose

First Aid Antibiotic

Uses:

First aid to help prevent infection in minor cuts, scrapes, and burns.

Warnings:

For external use only. Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center directly.

Do Not Use:

- in the eyes or over large areas of the body, or on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor
- if allergic to any of the ingredients

Stop use, ask a doctor if:

- condition persists or gets worse
- a rash or allergic reaction develops

Directions:

- clean affected area
- apply a small amount of this product (equal to the surface area of the tip of finger) 1 to 3 times daily
- may cover with a sterile bandage

Inactive ingredients:

mineral oil, petrolatum

Questions or Comments?

1-800-456-7077

Principal Display Panel - Box Label

NDC 61010-5601-2

Safetec

First Aid

Single Antibiotic Ointment

- with Bacitracin
- First Aid to Help Prevent Infection In Minor Cuts, Scrapes, and Burns

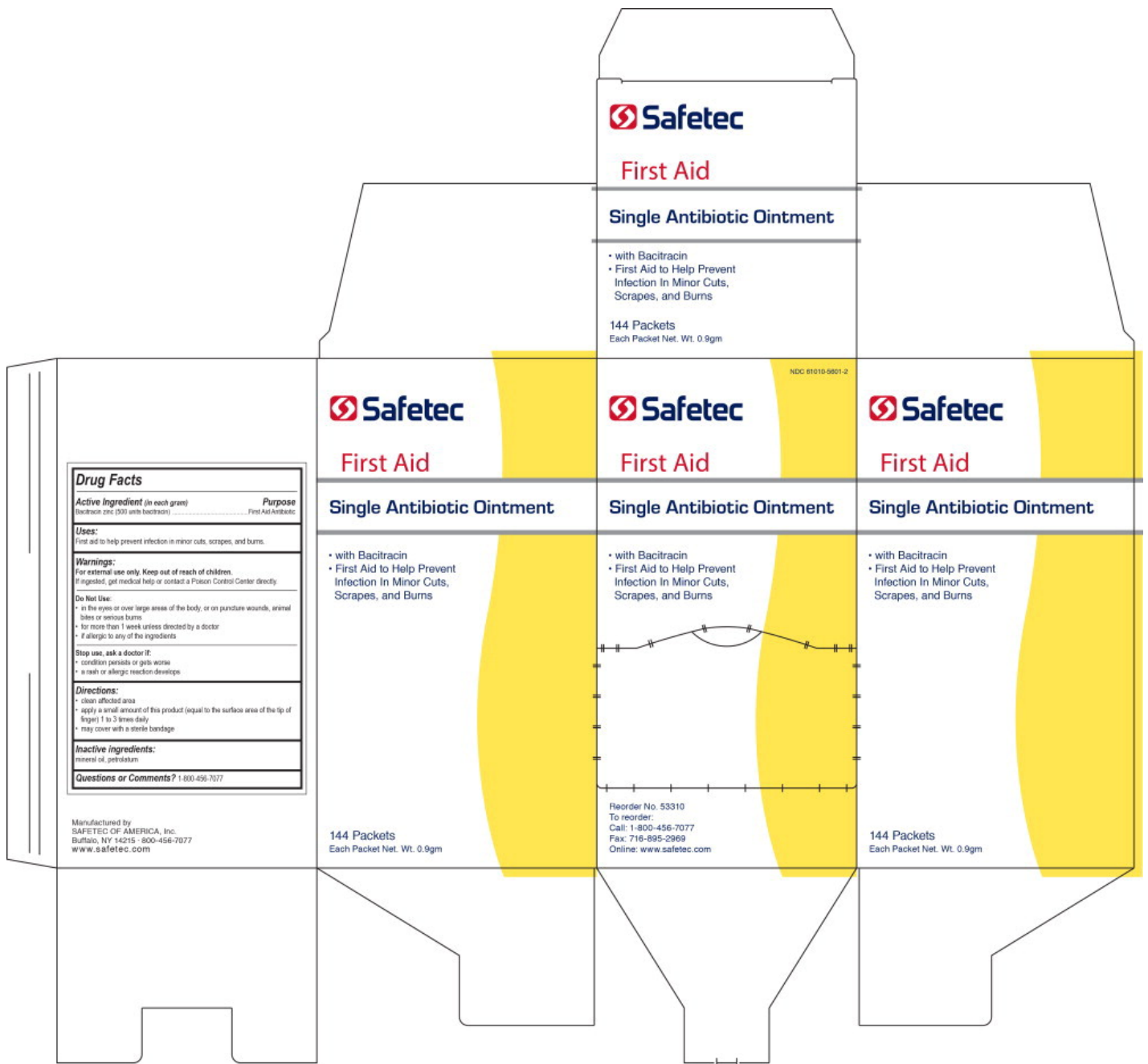
Reorder No. 53310

To reorder:

Call: 1-800-456-7077

Fax: 716-895-2969

Online: www.safetec.com



Principal Display Panel - Pouch Label

Safetec

**Single Antibiotic
Ointment**

(Bacitracin)

0.9 g (1/32 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077



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0.9 g (1/32 oz.)

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Buffalo, NY 14215
800-456-7077

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
(in each gram)	
Bacitracin zinc	First Aid
(500 units bacitracin).	Antibiotic

Use first aid to help prevent infection in minor scrapes, cuts, and burns

Warnings
For external use only ▶

Drug Facts (continued)

Warnings (continued)

Do not use ■ in eyes ■ over large areas of the body or on puncture wounds, animal bites or serious burns ■ for more than 1 week unless directed by a doctor ■ if you are allergic to any of the ingredients

Stop use and ask a doctor if ■ a rash or allergic reaction develops ■ condition worsens or persists

Keep out of reach of children
If ingested, contact a Poison Control Center right away.

Directions ■ clean affected area ■ apply a small amount 1 to 3 times daily ■ may cover with a sterile bandage

Inactive ingredients
mineral oil, petrolatum

Principal Display Panel - Box Label

NDC 61010-5601-3

Safetec

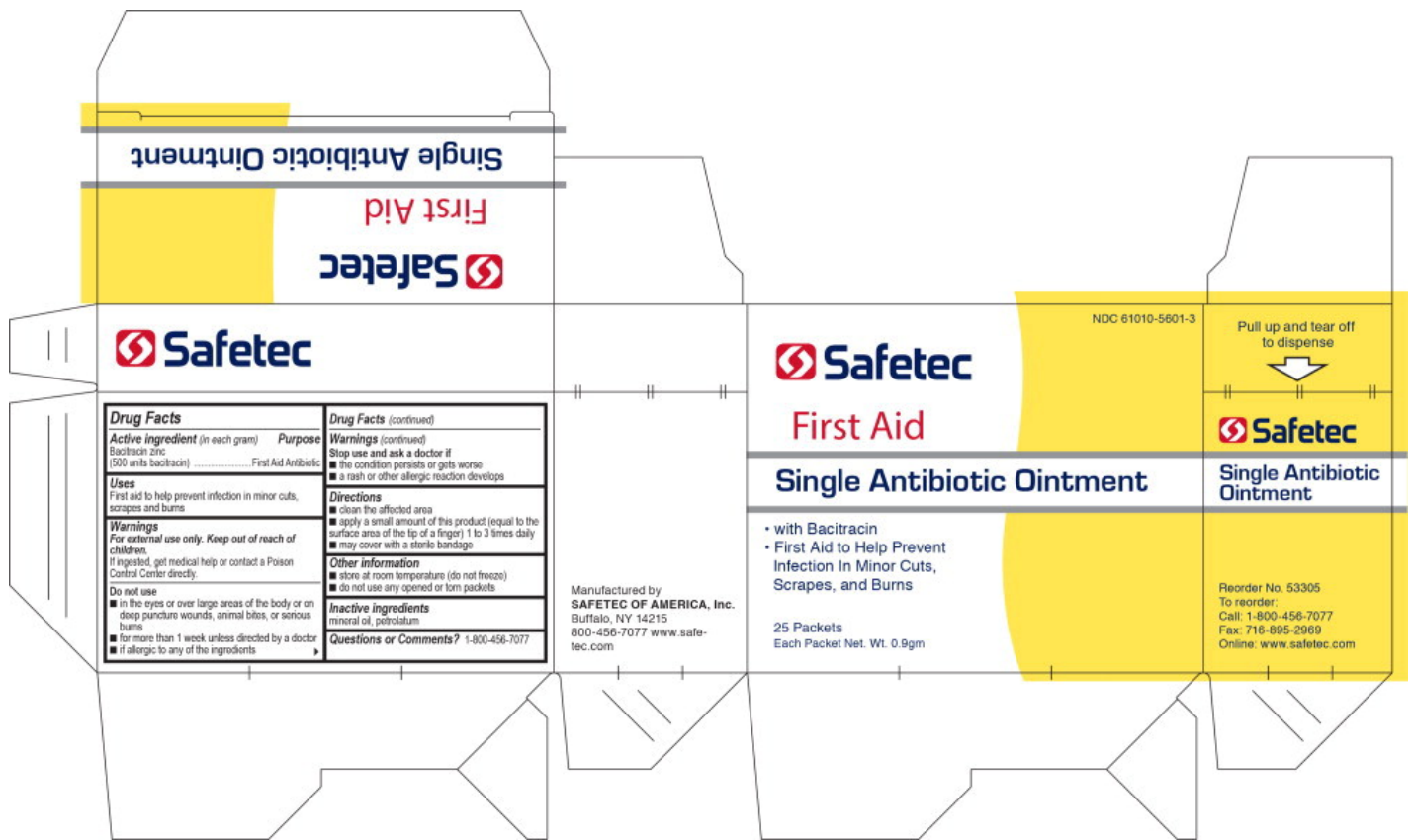
First Aid

Single Antibiotic Ointment

- with Bacitracin
- First Aid to Help Prevent Infection In Minor Cuts, Scrapes, and Burns

25 Packets

Each Packet Net. Wt. 0.9gm



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SINGLE ANTIBIOTIC WITH BACITRACIN

bacitracin zinc ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-5601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
bacitracin zinc (UNII: 89Y4M234ES) (bacitracin - UNII:58H6RWO52I)	bacitracin	400 [USP'U] in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-5601-2	144 in 1 BOX	11/13/2008	
1	NDC:61010-5601-1	0.9 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:61010-5601-3	25 in 1 BOX	11/13/2008	
2	NDC:61010-5601-1	0.9 g in 1 POUCH; 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	11/13/2008	

Labeler - Safetec of America (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(61010-5601)

Revised: 12/2019

Safetec of America