FIRST AID ANTISEPTIC- benzalkonium chloride and benzocaine spray
Provision Medical

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

Benzaikonium Chloride 0.1%

Benzocaine 5.0%

Purpose

First aid antiseptic

Topical pain relief

Uses

First aid to help prevent infection and for temporary pain relief in minor cuts, scrapes and burns

Warnings

For external use only.

Flammable keep away from fire or flame

Do not use

- near eyes or mucous membranes
- on deep or puncture wounds, animal bites, or serious burns
- over large areas of the body
- more than one week unless directed by a doctor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if condition persists or gets worse

Directions

- spray over cleaned affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 ask a doctor

Inactive ingredients

isopropyl alcohol, purified water

Principal Display Panel - Bottle Label

first aid

ANTISEPTIC
SPRAY

Treats Minor Cuts, Scrapes and Burns
Helps Prevent Infection and Relieves Pain

Package Not Child Resistant

2 fl. oz. (59.15ml)

Manufactured for

Provision Medical Products Palm Desert, CA 92211

FIRST AID ANTISEPTIC

benzalkonium chloride and benzocaine spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69103-3501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)	benzalkonium chloride	1 g in 1 L
benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)	benzocaine	50 g in 1 L

Inactive Ingredients	
Ingredient Name	Strength
isopropyl alcohol (UNII: ND2M416302)	
water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-3501-1	0.0591 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/29/2014	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-3501)

Revised: 8/2014 Provision Medical