ANTISEPTIC- benzalkonium chloride, 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

Benzalkonium 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

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

Inactive Ingredients

Principal Display Panel - 2 fl. oz Packet Label

The **Provision** First Aid Line™

Antiseptic Spray

For Temporary Pain Relief and to Help Prevent Infection in Minor Cuts, Scrapes and Abrasions.

2 fl. oz. (59.1 ml)

Reorder no. 3501

The Provision First Aid Line™		Drug FactsActive IngredientsPurposeBenzalkonium Chloride 0.1%Benzocaine 5.0%Topical pain reliefUsesFirst aid to help prevent infection and for temporary pain relief in minor cuts, scrapes and burns
Antiseptic S	pray	Warnings For external use only. Flammable keep away from fire or flame Do not use ■ near eyes or mucous membranes ■ on deep or
For Temporary Pain Relief and to Help		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.
Prevent Infection in Minor Cuts, Scrapes and Abrasions.		Stop use and ask a doctor if condition persists or gets worse
		<i>Directions</i> ■ clean affected area and spray 1 to 3 times daily ■ may be covered with a sterile bandage ■ children under 2 ask a doctor
0.4		Inactive Ingredients isopropyl alcohol, purified water
2 fl. oz. (59.1ml) Reorder no. 3501		Made for Provision Medical Products, LLC, Indio, CA 92211 1-888-602-0288

ANTISEPTIC

benzalkonium chloride, benzocaine spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69103-5300		

Active Ingredient/Active Moiety							
Ingredient Name Ba				Basis of Strength		Strength	
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y) benzalko					nzalko	nium chloride	1g in 1L
benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)benzoca				nzocai	ne	46 g in 1 L	
Inactive Ingredients							
Ingredient Name				Strength			
isopropyl alcohol (UNII: ND2M416302)							
water (UNII: 059Q	F0KO	OR)					
Packaging							
# Item Code		Package Description	1	Marketin Da	-		eting End Date
1 NDC:69103- 5300-0		91 L in 1 BOTTLE, SPRAY; Type 0: Not a bination Product	0	07/25/2022			
Marketing Information							
Marketing Category		Application Number or Monograph Citation	Ν	larketing Date			ting End ate
OTC monograph n final	ot	part333A	07/	25/2022			

Labeler - Provision Medical (036936831)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-5300)

Revised: 11/2013

Provision Medical