

FIRST AID ANTISEPTIC- benzalkonium chloride and benzocaine spray
Unishield

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
- 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

Questions?

call **1-800-480-5855**

Principal Display Panel - Bottle Label

UniShield

FIRST AID ANTISEPTIC SPRAY

TREATS:

- Minor Cuts
- Scrapes
- Scratches

HELPS:

- Prevent Infection
- Relieve Pain

NET CONTENTS 2 FL. OZ. (59.1 ML)

Distributed by: Unishield, San Francisco, CA 91340

Made in USA

UniShield

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49314-0098	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
benzalkonium chloride (UNII: F5UM2KM3W7) (benzalkonium - UNII:7N6JUD5X6Y)		benzalkonium chloride	1 mg in 1 g	
benzocaine (UNII: U3RSY48JW5) (benzocaine - UNII:U3RSY48JW5)		benzocaine	50 mg in 1 g	
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:49314-0098-1	59 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/27/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	01/27/2015		

Labeler - Unishield (790677053)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc		874965262	MANUFACTURE(49314-0098)