DG HEALTH- benzalkonium, lidocaine spray Inspec Solutions LLC.

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.

First Aid Antiseptic Spray

Active Ingredient

Benzalkonium CI 0.13%

Lidocaine 2.5%

When using this product

do not use in or near the eye

do not apply over large areas of the body or in large quantities

do not apply over raw surface or blistered areas

Benzalkonium CI 0.13% First Aid Antiseptic

Lidocaine 2.5% Pain Relieving Spray

Stop use and ask a doctor if

condition worsens

symptoms presist for over than 7 days, or clear up and occur sgain within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE

SODIUM PHOSPHATE DIBASIC

NONOXYNOL-9

EDETATE DISODIUM

purified Water

METHYLPARABEN

DIAZOLIDINYL UREA

PROPYLPARABEN

WARNINGS

For external use only.

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do not apply over raw surface or blistered areas

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condition worsens

symptoms presist for over than 7 days, or clear up and occur sgain within a few days

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Uses

Directions

first aid to help prevent bacterial contamination or skin infection, and for temporary relief of pain and itching associated with minor: cute, scrapes, burns, sunburn, skin irritations

Spray small amount on the area 1-3 times daily



DG HEALTH

benzalkonium, lidocaine spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	2.5 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 9425516E2T)			
NONOXYNOL-9 (UNII: 48Q180SH9T)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
METHYLPARABEN (UNII: A218C7H19T)			
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:72667- 006-01	148 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/01/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	01/01/2019		

Labeler - Inspec Solutions LLC. (081030372)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inspec Solutions LLC.		081030372	manufacture(72667-006)	

Revised: 6/2021 Inspec Solutions LLC.