MEDLINE- benzalkonium chloride, lidocain hydrochloride spray Medline Industries, LP

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.

919 Medline Burn Spray

Active ingredient

Benzalkonium chloride 0.13% w/w

Lidocaine HCl 4% w/w

Uses

- first aid to help prevent the risk of bacterial contamination in minor cuts, scrapes, and burns
- for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations

Warnings

For external use only.

Do not use

- in the eyes or apply over large areas of the body
- longer than 1 week, unless directed by a doctor
- in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have

deep puncture wounds, animal bites or serious burns

When using this product

- contents under pressure
- do not puncture or incinerate
- store at temperatures between 45°-130°F (7°-54°C), avoid excessive heat

Stop use and consult a doctor if

condition persists or gets worse

Keep out of reach of children.

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

Directions

clean the affected area

- spray a small amount of this product on the area 1 to 3 times a day
- may be covered with a sterile bandage
- if bandaged, let dry first

Inactive ingredients

aloe vera gel, camphor, propylene glycol, purified water USP, sodium hydroxide

Questions or comments?

1-800-MEDLINE Monday-Friday 8:30 a.m.-5:00 p.m. EST

Manufacturing Information

Manufactured for: Medline Industries, Inc.

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA of foreign and domestic materials

www.medline.com

1-800-MEDLINE

REF: MDSBURN4

V1RF21WIP

Purpose

First aid antiseptic

Topical pain reliever

Package Label

Drug Facts Active ingredients **Purpose** First Aid Antiseptic Benzalkonium chloride 0.13% Lidocaine HCI 4% Topical Pain Reliever Uses First aid to help prevent the risk of bacterial contamination in minor cuts, scrapes, and burns of for the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations. Warnings For external use only. Do not use ■ in the eyes or apply over large areas of the body ■ longer than 1 week, unless directed by a doctor in large quantities, particularly over raw surfaces or blistered areas. Ask a doctor before use If you have deep puncture wounds, animal bites, or serious burns When using this product ■ contents under pressure ■ do not puncture or incinerate ■ store at temperatures between 45°-130°F (7°-54°C) avoid excessive heat ■ keep out of reach of children. Stop use and consult a doctor If condition persists or gets worse. Directions ■ clean the affected area ■ spray a small amount of this product on the area 1 to 3 times a day ■ may be covered with a sterile bandage ■ if bandaged, let dry first. Inactive ingredients aloe vera gel, camphor, propylene glycol, purified water USP, sodium hydroxide Questions or comments? 1-800-MEDLINE Monday-Friday 8:30 a.m.-5:00 p.m. EST



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MEDLINE

benzalkonium chloride, lidocain hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-919
Poute of Administration	TOPICAL		

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g			
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g			

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
WATER (UNII: 059QF0KO0R)		
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		

	Packaging				
•	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:53329- 919-04	113 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/01/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	05/01/2021		

Labeler - Medline Industries, LP (025460908)

Revised: 7/2022 Medline Industries, LP