ALOCANE MAX- lidocaine hydrochloride and benzalkonium chloride spray Ouest Products LLC

Alocane ® Max Spray

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.13%	First Aid Antiseptic
Lidocaine HCL 4%	Topical Analgesic

Uses:

First aid to help prevent bacterial icontamination or skin infection, and for temporary relief of pain and itching associated with minor:

- Burns
- Cuts
- Sunburn
- Scrapes
- Minor Skin Irritation

Warnings

For external use only.

Ask a doctor before use if you have:

- Deep or puncture wounds
- Animal Bites
- Serious burns

Do not use:

- In or near the eyes
- In large quantities or over large areas of the body
- On raw surfaces or blistered areas

Stop use and ask doctor: if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If pregnant or breast-feeding, ask a health care professional before use.

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

Directions

Adults and children 2 years of age and older: Clean the affected area. Spray a small amount on the affected area 3 to 4 times daily. May be covered with a sterile bandage (let dry first). To apply to the face, spray on palm and apply.

Children under 2 years of age: ask a doctor.

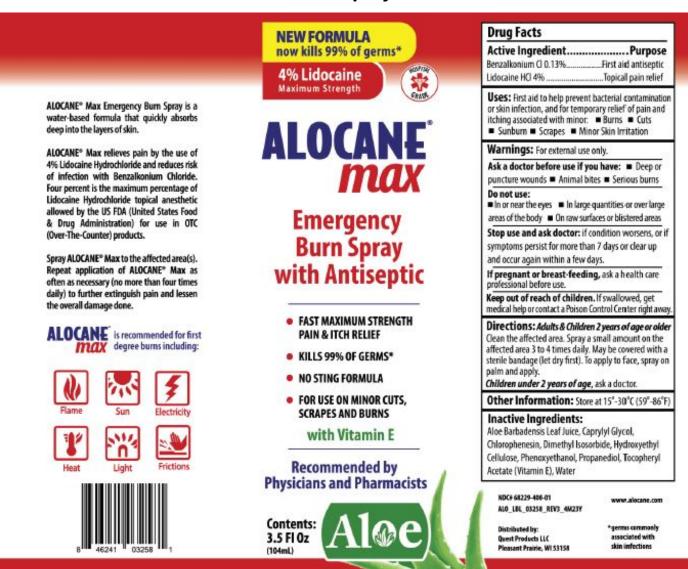
Other Information

Store at 15°-30°C (59°-86°F)

Inactive Ingredients

Aloe Barbadensis (Aloe) Leaf Juice, Caprylyl Glycol, Chlorphenesin, Dimethyl Isosorbide, Hydroxyethyl Cellulose, Phenoxyethanol, Propanediol, Tocopheryl Acetate (Vitamin E), Water.

PRINCIPAL DISPLAY PANEL - 3.5 fl oz spray



ALOCANE MAX

lidocaine hydrochloride and benzalkonium chloride spray

Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:68229-408
	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 mL	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.13 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
PROPANEDIOL (UNII: 5965N8W85T)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)			
HYDROXYETHYL CELLULOSE (5500 MPA.S AT 2%) (UNII: M825OX60H9)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
CHLORPHENESIN (UNII: 1670DAL4SZ)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68229- 408-01	104 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/15/2023	
2	NDC:68229- 408-02	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/15/2023	
3	NDC:68229- 408-03	124 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/15/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/15/2023	

Labeler - Quest Products LLC (075402441)

Establishment			
Name	Address	ID/FEI	Business Operations
Filltech USA, LLC		926433855	manufacture(68229-408)

Revised: 11/2023 Quest Products LLC