

ALOCANE BOTANICALS- lidocaine hydrochloride spray
Quest Products, 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.

Alocane® Botanicals

Drug Facts

Active Ingredient

Lidocaine HCL 4%

Purpose

Topical Pain Relief

Uses

For the temporary relief of pain and itching associated with:

- Sunburn
- Minor Skin Irritation
- Minor Burns
- Minor Cuts & Scrapes
- Insect Bites

Warnings

For external use only. Avoid contact with eyes.

Do not use:

- in large quantities, or over large areas of the body
- Over raw surfaces or blistered areas
- If you have an allergy to any of the ingredients

Ask a doctor before use if you have a severe burn or deep cut, broken or compromised skin

Stop use and ask doctor:

- if condition worsens
- if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

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

Directions:***Adults and Children 2 years of age or older:***

Shake well. Apply top affected area not more than 3-4 times daily. To apply to face, spray on palm and carefully apply.

Children under 2 years of age, ask a doctor before use.

Other Information

Store at 15-30°C (59-86°F)

Inactive Ingredients

Water, Phenoxyethanol, Aloe Vera Leaf Juice, Lactobacillus Ferment, Echinacea Purpurea Root Extract, Calendula Officinalis Flower Extract, Sodium Hyaluronate, D-Panthenol, Glycerin, Hydroxyethyl Cellulose, Mannitol, Sodium Hydroxide

PRINCIPAL DISPLAY PANEL -- Alocane Botanicals 4oz Spray Bottle



ALOCANE BOTANICALS

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68229-405
Route 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

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LIMOSILACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROXYETHYL CELLULOSE (5500 MPA.S AT 2%) (UNII: M825OX60H9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68229-405-01	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/11/2023	
2	NDC:68229-405-02	104 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/11/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/11/2023	

Labeler - Quest Products, LLC. (075402441)

Establishment

Name	Address	ID/FEI	Business Operations
Fill Tech USA		926433855	manufacture(68229-405)

Revised: 8/2023

Quest Products, LLC.