ALOE VERA GEL- lidocaine hcl, menthol gel Publix Super Markets, Inc.

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.

After Sun Gel

747

Active ingredient

Lidocaine HCl 0.7%

Menthol 0.2%

Purpose

Topical analgesic

Uses

for the temporary relief of pain and itching associated with

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

Warnings

For external use only

when using this product

avoid contact with the eyes

Do not use

in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

condition worsens, or 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

Directions

• adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

• children under 2 years of age: ask a doctor

Inactive ingredients

water, alcohol denat., polysorbate 20, glycerin, Aloe barbadensis leaf juice, carbomer, benzophenone-4, triethanolamine, benzyl alcohol, phenoxyethanol, blue 1

PUBLIX GUARANTEE:

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DISTRIBUTED BY

PUBLIX SUPER MARKETS, INC.,

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LAKELAND, FL 33811

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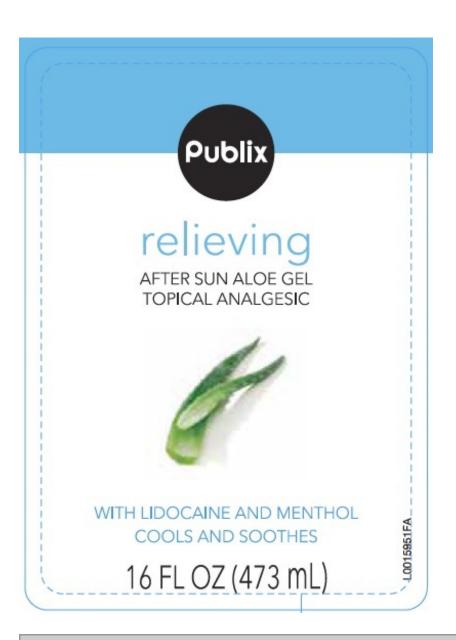
relieving

AFTER SUN GEL

TOPICAL ANALGESIC

WITH LIDOCAINE AND MENTHOL COOLS AND SOOTHES

16 FL OZ (473 mL)



ALOE VERA GEL

lidocaine hcl, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-747
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	7 mg in 1 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 mg in 1 mL	

Inacti	e Ingredients	
	Ingredient Name	Strength

water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
glycerin (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CARBOXYPOLYMETHYLENE (UNII: 0 A5MM307FC)	
SULISOBENZONE (UNII: 1W6L629B4K)	
TROLAMINE (UNII: 903K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
phenoxyethanol (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:56062-747- 43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	0 1/10/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 1/10/20 17	

Labeler - Publix Super Markets, Inc. (006922009)

Registrant - Vi-Jon (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon		790752542	manufacture(56062-747)	

Revised: 5/2020 Publix Super Markets, Inc.