# 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.

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# Pain Relieving Aloe Vera Gel 747.001/747AB

### Active ingredient

Lidocaine HCI 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:** 

COMPLETE SATISFACTION OR YOUR MONEY BACK

**DISTRIBUTED BY** 

PUBLIX SUPER MARKETS, INC.,

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LAKELAND, FL 33811

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# principal display panel

**Publix** 

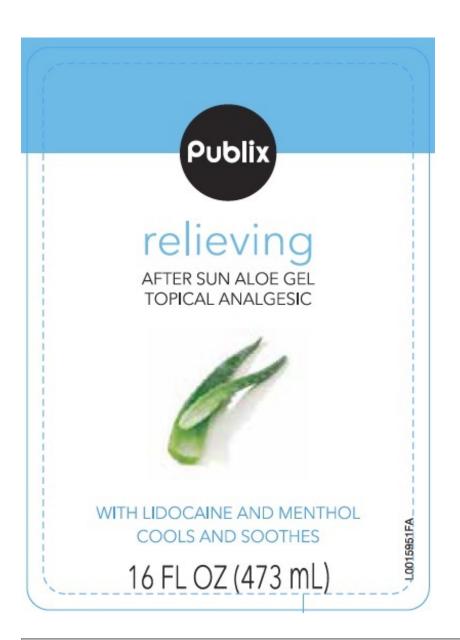
relieving

AFTER SUN GEL

TOPICAL ANALGESIC

WITH LIDOCAINE AND MENTHOL COOLS AND SOOTHES

16 FL OZ (473 mL)



# **ALOE VERA GEL**

lidocaine hcl, menthol gel

Pro						

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
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	7 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2 mg in 1 mL

nactive	Inared	lients

Ingredient Name Strength

water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
glycerin (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
SULISOBENZONE (UNII: 1W6L629B4K)	
TROLAMINE (UNII: 903K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
phenoxyethanol (UNII: HIE492ZZ3T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

l	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	01/10/2017				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	01/10/2017			

# Labeler - Publix Super Markets, Inc. (006922009)

# Registrant - Vi-Jon, LLC (790752542)

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

Establishment						
Name	Address	ID/FEI	Business Operations			
Vi-Jon, LLC		088520668	manufacture(56062-747)			

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