## BURNRELIEF- lidocaine hcl gel Publix

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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Sunburn Relief Gel 005.002/005AC-AD

## **Active ingredient**

Lidocaine HCI

### purpose

External analgesic

#### Use

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

## Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or clean 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, propylene glycol, glycerin, Aloe barbadensis leaf juice, triethanolamine, isopropyl alcohol, polysorbate 80, carbomer, diazolidinyl urea, menthol, disodium EDTA, blue 1, yellow 5

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PUBLIX GUARANTEE: COMPLETE SATISFACTION

OR YOUR MONEY BACK

## principal display panel

**Publix** 

burnrelief

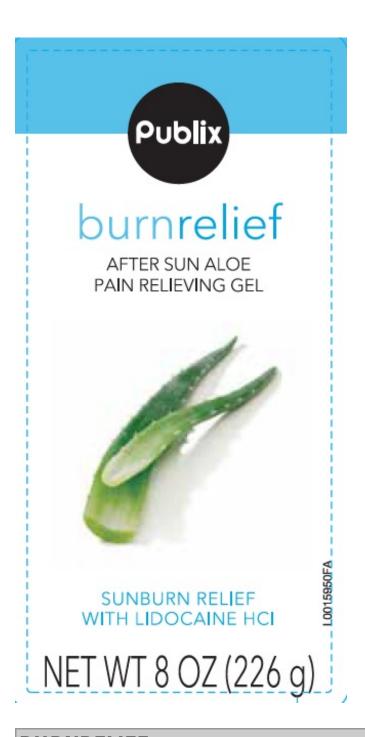
**AFTER SUN ALOE** 

PAIN RELIEVING GEL

**SUNBURN RELIEF** 

WITH LIDOCAINE HCI

NET WT 8 OZ (226 g)



# **BURNRELIEF**

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-942
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5.05 g in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
TROLAMINE (UNII: 903K93S3TK)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)			
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)			
MENTHOL (UNII: L7T10EIP3A)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		226 g in 1 BOTTLE, PUMP; 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	
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# **Labeler -** Publix (006922009)

# Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Vi-Jon, LLC		790752542	manufacture(56062-942)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(56062-942)

Revised: 9/2022 Publix