

## **PUBLIX BURN RELIEF ALOE VERA- lidocaine hydrochloride 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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### **Drug Facts**

#### **Active ingredient**

Lidocaine HCl 0.5%

#### **Purpose**

Topical Analgesic

#### **Uses**

- temporary relief of pain and itching
- helps relieve and soothes pain from sunburn, minor burns, cuts, scrapes, skin irritations and insect bites

#### **Warnings**

##### **For external use only**

##### **Do not use**

in large quantities, particularly over raw surfaces or blistered areas.

##### **When using this product**

- avoid contact with eyes

##### **Stop use and ask a doctor if**

- condition worsens or if symptoms persist for more than 7 days.
- symptoms 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 areas not more than 3 to 4 times daily
- children under 2 years of age: do not use, ask a doctor

#### **Inactive ingredients**

Water, Propylene Glycol, Glycerin, Isopropyl Alcohol, Triethanolamine, Polysorbate 80, Carbomer, Aloe Barbadensis Leaf Juice Powder, Menthol, Disodium EDTA, Diazolidinyl Urea, Yellow 5, Blue 1.

**Principal Display Panel**

publix

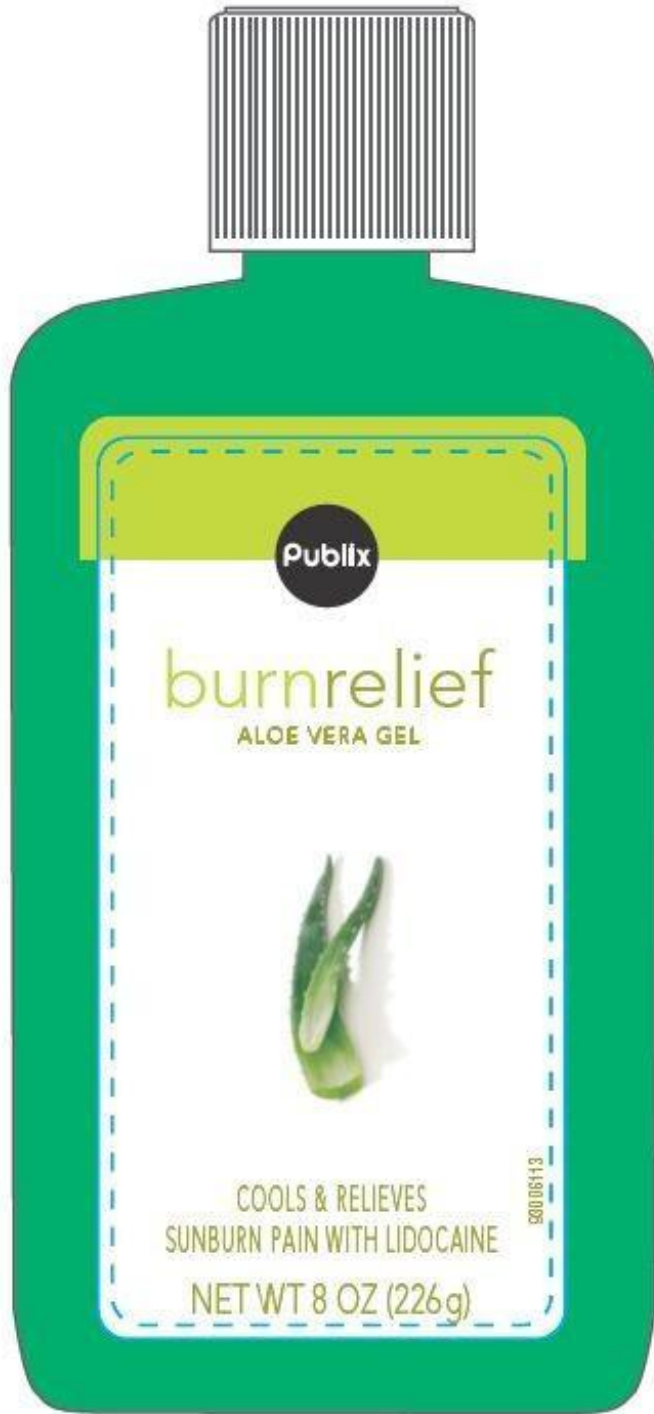
burn relief


ALOEVERA GEL

COOLS AND RELIEVES

SUNBURN PAIN WITH LIDOCAINE

NET WT 8 OZ(226 g)



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<b>Active ingredient</b> Lidocaine HCl 0.5%	<b>Purpose</b> Topical Analgesic
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DASHED LINE INDICATES  
PRINT AREA (1/16TH IN.  
FROM DIELINE)

## PUBLIX BURN RELIEF ALOE VERA

lidocaine hydrochloride gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:56062-711
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MENTHOL (UNII: L7T10EIP3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-711-19	226 g in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/12/2013	

**Labeler** - Publix Super Markets Inc (006922009)

Revised: 7/2013

Publix Super Markets Inc