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.

Sunburn Relief Gel
005.002/005AC-AD

Active ingredient

Lidocaine HCl

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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OR YOUR MONEY BACK

principal display panel

Publix

burnrelief

AFTER SUN ALOE

PAIN RELIEVING GEL

SUNBURN RELIEF

WITH LIDOCAINE HCl

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: 9O3K93S3TK)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
MENTHOL (UNII: L7T10EIP3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-942-34	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	

Labeler - Publix (006922009)

Registrant - Vi-Jon, LLC (790752542)

Establishment

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

Establishment

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

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