PUBLIX BURN RELIEF - lidocaine hcl 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.

Drug Facts

Active ingredient

Lidocaine HCL 0.50%

Purpose

Topical Anesthetic

Uses

- temporary relief of pain and itching
- helps relieve and soothes pain from sunburn, minor burns, cuts, scrapes, skin irritations and inspect 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 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 Poison Control Center immediately.

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: do not use, ask a doctor

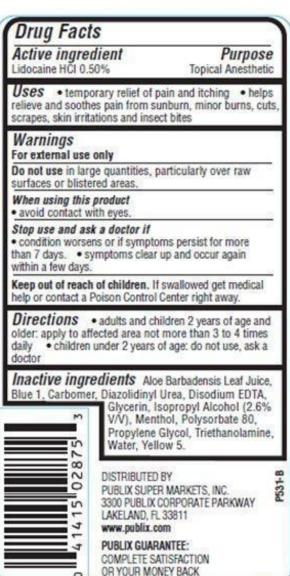
Inactive ingredients

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

Principal Display Panel

Publix burnreilef ALOE VERA GEL COOLS AND RELIEVES SUNBURN PAIN WITH LIDOCAINE





PUBLIX BURN RELIEF

lidocaine hcl gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-701	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
GLYCERIN (UNII: PDC6A3C0OX)		
MENTHOL (UNII: L7T10EIP3A)		
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-701-16	227 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	11/15/2012		

Labeler - Publix Super Markets Inc (006922009)

Revised: 11/2012 Publix Super Markets Inc