PUBLIX BURN RELIEF - lidocaine and 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.

Drug Facts

Active ingredients

Lidocaine 0.50% Menthol 0.10%

Topical Anesthetic

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 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, Alcohol Denat., Propylene Glycol, Glycerin, Polysorbate 20, Carbomer, Triethanolamine, Diazolidinyl Urea, Aloe Barbadensis Leaf Juice, Tocopherol, Disodium EDTA, Blue 1.

Principal Display Panel

Publix relieving ALOE VERA GEL SOOTHES PAIN WITH LIDOCAINE AND MENTHOL NET WT 16 OZ (454g)







SOOTHES PAIN WITH LIDOCAINE & MENTHOL

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Purpose

Menthol 0.10%

Topical Anesthetic Topical Analgesic

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- . children under 2 years of age: do not use, ask a doctor

Inactive ingredients Alos

Barbadensis Leaf Juice, Blue 1, Carbomer, Diazolidinyl Urea, Disodium EDTA, Glycerin, Polysorbate 20, Propylene Glycol, SD Alcohol 40-B (12.2% V/V), Tocopherol, Triethanolamine, Water.

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PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

SDA-FL-386



PUBLIX BURN RELIEF

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:56062-702
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (LIDO CAINE)	LIDOCAINE	0.5 g in 100 g	
MENTHOL (MENTHOL)	MENTHOL	0.1 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF			
FD&C BLUE NO. 1			
DIAZO LIDINYL UREA			
EDETATE DISO DIUM			
GLYCERIN			
POLYSORBATE 20			
PROPYLENE GLYCOL			
TOCOPHEROL			
TROLAMINE			
WATER			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:56062-702-16	454 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