SUNBURN RELIEF- lidocaine hcl 0.5% gel Rite Aid

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 0.5%

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

Do not use

in large quantities, particularly over raw surfaces or blistered areas

When using this product

avoid contact with the eyes

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more than 7 days or 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 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, phenoxyethanol, benzyl alcohol, menthol, disodium EDTA, blue 1, yellow 5

*This product is not manufactured or distributed by Bayer

distributer of Solarcaine Cool Aloe Burn Relief Formula

DISTRIBUTED BY: RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

www.riteaid.com

SATISFACTION GUARANTEE:

If you're not satisfied,

we'll happily

refund your money.

Principal Panel Display

Compare to Salarcaine

Cool Aloe Burn Relief Formula

Pain Relieving Gel

with Lidocaine HCI*

SUNBURN

RELIEF

PAIN RELIEVING GEL

WITH ALOE

Cool on contact

Great sunburn relief

Minor burn relief

NET WT

8 OZ (226 g)



SUNBURN RELIEF

lidocaine hcl 0.5% gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0776	
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 mg 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)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
phenoxyethanol (UNII: HIE492ZZ3T)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
MENTHOL (UNII: L7T10EIP3A)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:11822- 0776-3	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2019	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/30/2019	

Labeler - Rite Aid (014578892)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-0776)

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Revised: 10/2022 Rite Aid