

SUNBURN RELIEF GEL- lidocaine hcl gel

CVS

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.

CVS 005.002/025AC-AD Sunburn Relief Gel

Active ingredient

Lidocaine HCl 0.5%

Purpose

External analgesic

Uses

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

When using this product

avoid contact with the eyes

Do not use

in large quantities, particularly over raw surfaces or blistered areas

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

disclaimer

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principal display panel

CVS

Health

Compare to the active ingredient in Solarcaine Cool Aloe Relief Formula

Burn

Relief Gel

LIDOCAINE HCl 0.5%

Pain Relieving Gel

Moisturizing Gel

- Soothes & relieves
- Cools & soothes sunburned skin
- Paraben free

NET WT 8 OZ (226 g)



SUNBURN RELIEF GEL

lidocaine hcl gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-909
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z 41A) (LIDOCAINE - UNII: 98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5.05 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
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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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
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:69842-909-34	226 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/31/2018	

Labeler - CVS (062312574)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(69842-909)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(69842-909)