SUNBURN RELIEF- lidocaine hcl 0.5% gel
Old East Main CO

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.

Dollar General_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

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 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, distributor of Solaraine Cool Aloe Burn Relief Formula

Distributed By Old East Main Co.

100 MISSION RIDGE, GOODLETTSVILLE, TN 37072

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principal display panel

DS|health

Compare to Solarcaine*

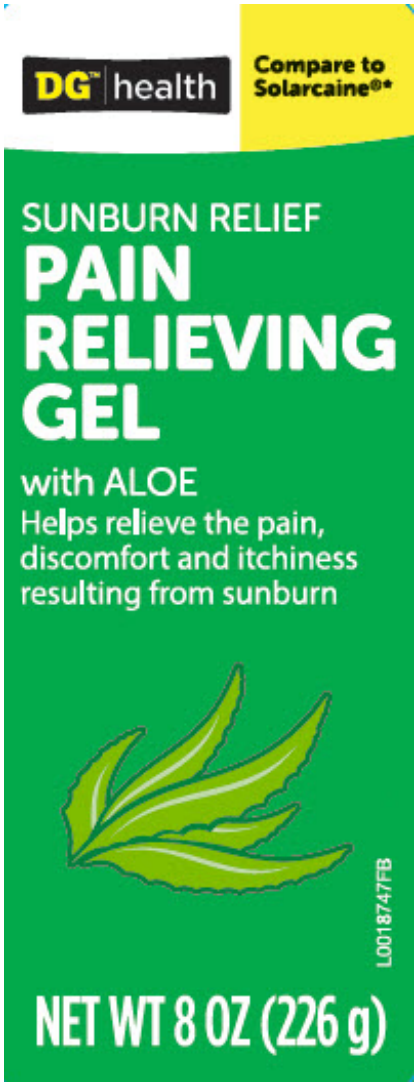
SUNBURN RELIEF

PAIN RELIEVING GEL

with ALOE

Helps relieve the pain, discomfort and itchiness resulting from sunburn

NET WT 8 OZ (226 g)



SUNBURN RELIEF

lidocaine hcl 0.5% gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55910-177
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5.00 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: 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 ANHYDROUS (UNII: 8NLQ36F6MM)	
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:55910-177-34	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2019	

Marketing Information

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

Labeler - Old East Main CO (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-177)

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Revised: 1/2023 Old East Main CO