

SUNBURN RELIEF- lidocaine 0.5% spray

Topcare

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 0.5%

Purpose

External analgesic

Uses

Temporarily relieves pain and itching due to

- sunburn • minor burns • minor cuts • scrapes
- insect bites • minor skin irritation

Warnings

For external use only

Flammable: Do not spray while smoking or near heat or flame

Do not use in large quantities, particularly over raw surfaces or blistered areas.

When using this product

- keep out of your eyes
- use only as directed
- do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120F.

Keep out of reach of the children

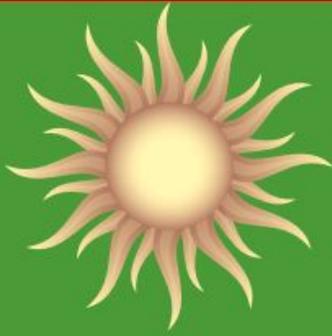
If swallowed, get medical help or contact a Poison Control Center right away

Directions

- shake well
- 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
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

Aloe Barbadensis Leaf Juice, Carbomer, Diazolidinyl Urea, Disodium Cocoamphodipropionate, Disodium EDTA, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 40, Simethicone, Tocopheryl Acetate, Triethanolamine



TopCare®

sunburn relief

LIDOCAINE 0.5%
PAIN RELIEVING
CONTINUOUS SPRAY

- enriched with aloe
provides fast relief from:
- sunburn • cuts & scrapes
 - insect bites • minor burns

COOLING

*COMPARE TO THE ACTIVE
INGREDIENT IN SOLARCAINE®

NET WT 6 OZ (170 g)

Drug Facts

Active ingredient	Purpose
Lidocaine 0.50%	External analgesic

Uses Temporarily relieves pain and itching due to:

- sunburn • minor burns • minor cuts • scrapes
- insect bites • minor skin irritations

Warnings

For external use only

Flammable: Do not use near heat, flame, or while smoking.

Do not use in large quantities, particularly over raw surfaces or blistered areas

When using this product • keep out of eyes • use only as directed. • do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- shake well • 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 • to apply to face, spray into palm of hand and gently apply

Inactive ingredients

Aloe Barbadosis Leaf Extract, Carbomer, Diazolidinyl Urea, Disodium Cocoamphodipropionate, Disodium EDTA, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 40, Simethicone, Tocopheryl Acetate, Triethanolamine.

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ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

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SUNBURN RELIEF

lidocaine 0.5% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-721
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	Lidocaine	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Disodium Cocoamphodipropionate (UNII: 6K8PRP397M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-721-05	170 g in 1 CAN; Type 0: Not a Combination Product	12/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/29/2016	

Labeler - Topcare (006935977)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(36800-721) , label(36800-721)