INSTANT BURN RELIEF- lidocaine 0.5% spray Care One

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 Purpose

Lidocaine 0.5% 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, particulary 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

Questions? 1-877-846-9949



Drug Facts

Active ingredient
Lidocaine 0.5%

PurposeExternal analgesic

Uses For the temporary relief of pain and itching associated with: • sunburs
• 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

When using this product • keep away from face to avoid breathing it. • avoid contact with eyes. • use only as directed. • do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

If condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a doctor.

Keep out of reach of 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: consult a doctor • Do not spray directly into face; spray into palm of hand and gently apply

Inactive ingredients Aloe Barbadensis Leaf Extract, Carbomer, Diazolidinyl Urea, Disodium Occamphodipropionate, Disodium EDTA, Glycerin, Methylparaben, Propylene Glycol, Propyleparaben, SD Alcohol 40, Simethicone, Tocopheryl Acetate, Triethanolamine.

Questions? 1-877-846-9949

*This product is not manufactured or distributed by Bayer Consumer Care, LLC., distributor of Solarcaine®.

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INSTANT BURN RELIEF

lidocaine 0.5% spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-348

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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		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: ZY8 1Z8 3H0 X)		
Diazolidinyl Urea (UNII: H5RIZ3MPW4)		
Disodium Cocoamphodipropionate (UNII: 6K8 PRP39 7M)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
Glycerin (UNII: PDC6A3C0OX)		
Methylparaben (UNII: A2I8 C7HI9 T)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Propylparaben (UNII: Z8IX2SC1OH)		
ALCOHOL (UNII: 3K9958V90M)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 9O3K93S3TK)		

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1 NDC:41520-348-05	170 g in 1 CAN; Type 0: Not a Combination Product	03/15/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2017	

Labeler - Care One (809183973)

Registrant - Product Quest Mfg (927768135)

Establishment				
Name	Address	ID/FEI	Business Operations	
Product Quest Mfg		927768135	manufacture(41520-348), label(41520-348)	

Revised: 7/2018 Care One