ALOE BURN RELIEF- lidocaine 0.5% spray DZA Brand

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.

Stop use and ask a doctor if

- condition gets worse
- symptoms last more than 7 days
- symptoms clear up and occur again within a few days

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? 1-866-322-2439







lidocaine 0.5% external analgesic

- instant pain relief with lidocaine
- · for minor burns, cuts, scrapes & itching

Compare to Solarcaine® active ingredient*



NET WT 4.5 OZ (127 g)

ALOE BURN RELIEF

lidocaine 0.5% spray

Product Informat	tion
------------------	------

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:55316-777

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLidocaine (UNII: 98 PI200987) (LIDOCAINE - UNII:98 PI200987)Lidocaine0.5 g in 100 g

Inactive Ingredients

Ingredient Name

Strength

ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)

` '	
Diazolidinyl Urea (UNII: H5RIZ3MPW4)	
Disodium Cocoamphodipropionate (UNII: 6K8PRP397M)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 903K93S3TK)	

ı	Packaging						
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
ı	1 NDC:55316-777-04	127 g in 1 CAN; Type 0: Not a Combination Product	10/10/2011				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part348	10/10/2011				

Labeler - DZA Brand (090322194)

Registrant - Product Quest Mfg (927768135)

Establishment					
Name	Address	ID/FEI	Business Operations		
Product Quest Mfg		927768135	manufacture(55316-777), label(55316-777)		

Revised: 7/2018 DZA Brand