BURN RELIEF- lidocaine 0.5% spray
Quality Choice

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? 248-449-9300

BURN RELIEF

lidocaine 0.5% spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-784
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:63868-784-04	127 g in 1 CAN; Type 0: Not a Combination Product	04/17/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/17/2012	

Labeler - Quality Choice (011920774)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(63868-784) , label(63868-784)

Revised: 7/2018 Quality Choice