BURN RELIEF- lidocaine spray
Amerisource Bergen

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

For the temporary relief of pain and itching associated with: • 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 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 120ºF.
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 Cocoamphodipropionate, Disodium EDTA, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, SD Alcohol 40, Simethicone, Tocopheryl Acetate, Triethanolamine.

Questions? 610-727-7000

BURN RELIEF

lidocaine spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:24385-777
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 (UNII: V5VD430YW9)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
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:24385-777-04	128 g in 1 CAN; Type 0: Not a Combination Product	03/15/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/15/2012	

Labeler - Amerisource Bergen (007914906)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(24385-777) , label(24385-777)

Revised: 7/2018 Amerisource Bergen