BURN RELIEF LEADER- lidocaine spray
Cardinal Health

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

Lidocaine 0.50%

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 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 eyes, use only as directed, do not puncture or incinerate. Contents under pressure. Do no store at temperatures above 120 deg F. **Stop use and ask doctor if**: condition gets worse, symptoms last more than 7 days, or symptoms clear up and occur again in a few days.

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

Purpose

External analgesic.

Keep out of reach of children.

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

Burn Relief Spray with Lidocaine.

BURN RELIEF LEADER

lidocaine spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-613
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	.05 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Aloe (UNII: V5VD430YW9)	
Alcohol (UNII: 3K9958V90M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Edetate Disodium (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-613-11	127 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	12/01/2011	

Labeler - Cardinal Health (097537435)

Revised: 1/2011 Cardinal Health