BURN WITH ALOE- lidocaine hydrochloride spray
Provision Medical

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

Lidocaine HCI 2,0%

Purpose

Topical pain relief

Uses

temporary pain relief associated with minor burns

Warnings

For external use only.

Do not use

- in large quantities, particularly over raw or blistered areas
- near eyes, if this happens rinse thoroughly with water

Stop use and ask a doctor if condition worsens or persists for more than 7 days or clears up and returns

Keep out of reach of children.

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

Directions

- adults and children 2 years of age and older: spray an even layer of burn spray over cleaned affected area not more than 3-4 times daily
- for children under 2 years of age: consult a physician

Inactive ingredients

aloe vera, germaben II, propylene glycol, purified water

Principal Display Panel - Bottle Label

with aloe vera

BURN SPRAY

Relieves Pain in Minor Burns

Washable

Package Not Child Resistant

2 fl. oz. (59.15ml)

Manufactured for

Provision Medical Products Palm Desert, CA 92211

BURN WITH ALOE

lidocaine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69103-3500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	200 g in 1 L

Inactive Ingredients	
Ingredient Name	**Strength**
aloe vera leaf (UNII: ZY81Z83H0X)	

propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
methylparaben (UNII: A2I8C7HI9T)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-3500-1	0.05915 L in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/29/2014	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-3500)

Revised: 7/2014 Provision Medical