

BURN- lidocaine hydrochloride spray

Acme United Corp

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 HCl 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 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

Questions?

call 203-857-5361

Principal Display Panel - Bottle Label

13-040

BURNS

FIRST AID ONLY®

Burn Spray

Pain relieving spray
for use on minor burns

4 fl oz (118.3ml)



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Questions? 1.800.835.2263

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www.FirstAidOnly.com
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T31169-040-revB

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BURN

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-0930
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	20 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0930-01	0.1183 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/06/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/06/2014	

Labeler - Acme United Corp (001180207)

Registrant - Safetec of America, Inc (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc		874965262	MANUFACTURE(0924-0930)

Revised: 10/2014

Acme United Corp