LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride gel
Acme United Corporation

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.

Burn Gel
Pain Relief

Drug Facts

Active ingredients

Lidocaine HCl 2%

Purpose

Topical pain relief

Uses

Temporary pain relief of minor burns. For professional use only.

Warnings

For external use only. Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center directly

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 doctor if

- the condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Directions

Adults and children 2 years and over: apply to affected area not more than 3 to 4 times daily

Children under 2 years: do not use, consult a doctor

Other information

- store at room temperature (do not freeze)
- do not use any opened or torn packs

Inactive ingredients

aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, Vitamin E acetate

Principal Display Panel - Pouch Label

***FIRST AID ONLY*®**

Burn Gel

For Temporary
Pain Relief of
Minor Burns

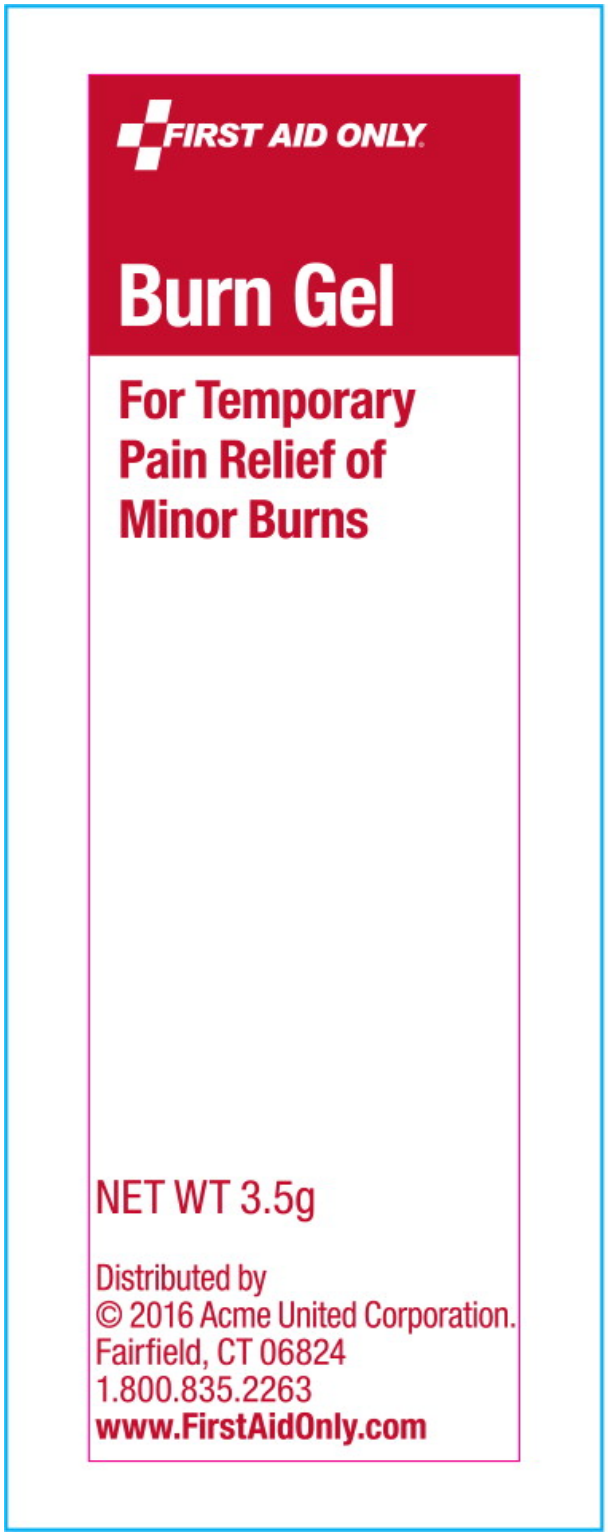
NET WT 3.5g

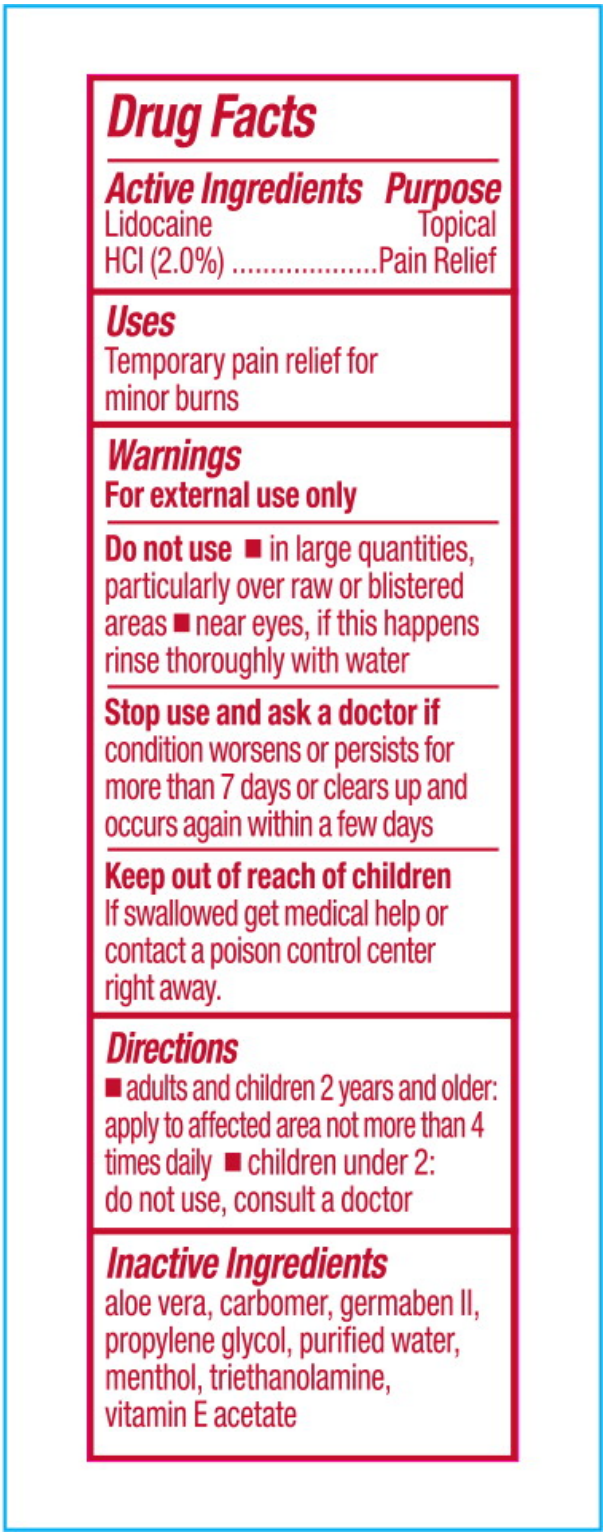
Distributed by

Fairfield, CT 06824

1.800.835.2263

www.FirstAidOnly.com





LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-5000
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 g

Inactive Ingredients	
Ingredient Name	**Strength**
aloe vera leaf (UNII: ZY81Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0KO0R)	
menthol (UNII: L7T10EIP3A)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
trolamine (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0924-5000-01	6 in 1 BOX	02/14/2013	
1	NDC:0924-5000-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5000-02	25 in 1 BOX	02/14/2013	
2	NDC:0924-5000-00	3.5 g in 1 PACKET; 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	02/14/2013	

Labeler - Acme United Corporation (001180207)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(0924-5000)

Revised: 3/2016 Acme United Corporation