LIDOCAINE HYDROCHLORIDE GEL- paraaid burn relief gel gel MCURE HEALTH SOLUTIONS INC.

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.

MCURE HEALTH SOLUTIONS INC.

20189 CURRIER ROAD, SUITE 200

CITY OF INDUSTRY, CA 91789

Active Ingredient Purpose

Lidocaine HCI 2.0% Topical Pain Relief

Uses

Temporary pain relief for minor burns

Directions

- Adults and children 2 years and older: apply 3 to 4 times daily
- Children under 2: do not use, consult with a doctor

Inactive Ingredients

Aloe vera, carbomer, germaben II, propylene glycol, purified water, menthol, triethanolamine, vitamin E acetate

Warnings

For external use only.

Keep out of reach of childre.

Do not use

- near eyes, if this happens, rinse thoroughly with water
- in large quantities, particularly over raw or blistered areas. Stop use, ask a doctor
- if condition worsens or lasts more than 7 days or clears up and returns. If ingested, contact a poison control center directly

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



BURN GEL

Enriched with Aloe Vera For Fast Relief of Minor Burns Cools and Soothes

Drug Facts

Active Ingredient Purpose

Lidocaine **Topical** HCI 2.0% Pain Relief

Uses

 Temporary pain relief for minor burns

Warnings

For external use only. Keep out of reach of children

MCURE Health Solutions, Inc. 20819 Currier Road, Suite 200 City of Industry, CA 91789

> 0.9 g(1/32 oz.)

Drug Facts (continued)

Warnings (continued)

Do not use ● near eyes, if this happens, rinse thoroughly with water • in large quantities, particularly over raw or blistered areas. Stop use, ask a doctor if condition worsens or lasts more than 7 days or clears up and returns. If ingested, contact a poison control center directly.

Directions

- Adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily
- Children under 2: do not use. consult with a doctor

Inactive Ingredients Aloe vera, carbomer, germaben II propylene glycol, purified water, menthol, triethanolamine, vitamin É acetate

LOT:

EXP:

LIDOCAINE HYDROCHLORIDE GEL

paraaid burn relief gel gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52486-008

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active wholety			
	Ingredient Name	Basis of Strength	Strength
	LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	2 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
CARBOMER 1342 (UNII: 809 Y72KV36)				
MENTHOL (UNII: L7T10 EIP3A)				
TRIETHANO LAMINE BENZO ATE (UNII: M3EN4GC19W)				
PROPYLENE GLYCOL 1-BEHENATE (UNII: 293K4PAQ2T)				
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:52486-008-02	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/01/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2016	

Labeler - MCURE HEALTH SOLUTIONS INC. (053034873)

Registrant - MCURE HEALTH SOLUTIONS INC. (053034873)

Revised: 5/2016 MCURE HEALTH SOLUTIONS INC.