

LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride gel
Dealmed Medical Supplies LLC

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%)

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 right away.

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

Directions

- for 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: do not use, consult a doctor

Other information

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

Inactive ingredients

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

Questions or Comments?

1-800-456-7077

Principal Display Panel - 0.9g Box Label

NDC 70082-500-01

dealmed

Burn

Gel

**For temporary relief
of minor burns**

144

PACKETS

NET WT. 0.9g

PER PACKET



Principal Display Panel - 0.9g Pouch Label

dealmed

Burn Gel

0.9g (1/32 oz.)

Dealmed • Brooklyn, NY

www.dealmed.com



0.9g (1/32 oz.)

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www.dealmed.com

Drug Facts

Active Ingredient	Purpose
Lidocaine HCl 2.0%	Topical pain relief

Uses Temporary pain relief for minor burns

Warnings
External use only. Keep out of reach of children.

Drug Facts (continued)

Warnings

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 conditions worsen or last 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 now more than 3 to 4 times daily ■ children under 2: do not use, ask a doctor

Inactive Ingredients aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, vitamin E acetate

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70082-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	18 mg in 1 g
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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:70082-500-01	144 in 1 BOX	03/18/2022	
1		0.9 g in 1 POUCH; 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	03/18/2022	

Labeler - Dealmed Medical Supplies LLC (068586441)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(70082-500)

Revised: 3/2022

Dealmed Medical Supplies LLC