

BURN- lidocaine hydrochloride gel
J&A Digital Inc.

Burn

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 the 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 a Poison Control Center right away.

Directions

- apply an even layer of gel over cleaned affected area
- not to be used on children under 12 years

Inactive ingredients

Aloe Barbadosis Leaf Juice, Carbomer, Ethylhexylglycerin, Maltodextrin, Menthol, Polyethylene Glycol, Phenoxyethanol, Triethanolamine, Tocopheryl Acetate, Water.

BURN

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82942-1001
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)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82942-1001-1	0.9 g in 1 PACKET; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	10/01/2022	

Labeler - J&A Digital Inc. (040268672)

Registrant - J&A Digital Inc. (040268672)