BURN- lidocaine hydrochloride gel
Yiwu Ori-Power Medtech Co., Ltd.

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 Hydrochloride 2%

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 burn gel over deaned affected area not more than 3-4 times daily
- not to be used on children under 12 years of age.

Inactive ingredients

Aloe BarbadensisLeaf Juice, Carbomer, Ethylhexgilglycerin, Maltodextrin, Menthol,

Polyethylene Glycol, Phenoxyethanol, Triethanolamine, Tocopheryl Acetate, Water.

BURN
lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72459-101
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: 3WQ0SDW1A)	
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:72459-101-01	0.9 g in 1 POUCH; Type 0: Not a Combination Product	08/28/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/28/2023	

Labeler - Yiwu Ori-Power Medtech Co., Ltd. (560451976)

Revised: 8/2023 Yiwu Ori-Power Medtech Co., Ltd.