LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride liquid
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.

First Aid Only Burn Spray

Drug Facts

Active ingredients

Lidocaine HCl 2.0%

Purpose

Topical pain relief

Use

Temporarily relieves pain associated with minor burns.

Warnings

For external use only.

Do not use

- in eyes, if contact occurs rinse thoroughly with water
- in large quantities, particularly over raw or blistered areas

Stop use and ask a doctor if 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 Poison Control Center right away

Directions

- adults and children 2 years of age and older: spray an even layer of burn spray over affected area not more than 3-4 times daily
- children under 2 years of age: consult a doctor

Inactive ingredients

aloe vera, diazolidinyl urea, propylene glycol, purified water

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Questions? 1.800.835.2263

Bottle

Label

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-0934(NDC:61010-5100)
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-0934-01	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/16/2023	
2	NDC:0924-0934-02	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/16/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/16/2023	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-0934) , repack(0924-0934)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-0934) , repack(0924-0934)

Revised: 1/2023 Acme United Corporation