

**FIRST AID ONLY BURN MIST- lidocaine hydrochloride spray**  
**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.*

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**First Aid Only Burn Spray**

**Active ingredient**

Lidocaine HCl 2%

**Purpose**

External analgesic

**Uses**

for the temporary relief of pain associated with minor burns

**Warnings**

**For external use only**

**Do not use**

in large quantities, particularly over raw surfaces or blistered areas

**When using this product**

avoid contact with eyes

**Stop use and ask a doctor if**

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

**Keep out of the reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- 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: consult a doctor

**Other information**

- store at room temperature

**Inactive ingredients**

diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine

**Questions**

800.835.2263

**Principal Display Panel**

**Bottle Label BurnSpray 2018.jpg**

Bottle Label BurnSpray 2018.jpg

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Lidocaine HCl 2% .....	External analgesic
<b>Uses</b> for the temporary relief of pain associated with minor burns	
<b>Warnings</b>	
For external use only	
Avoid contact with the eyes	
Do not use in large quantities, particularly over raw surfaces or blistered areas	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> <li>■ condition worsens ■ symptoms persist more than 7 days</li> <li>■ condition clears up and occurs again within a few days</li> </ul>	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ 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: consult a doctor	
<b>Other information</b> ■ store at room temperature	
<b>Inactive ingredients</b> diazolidinyl urea, edetate disodium, glycerin, hypromellose, methylparaben, octoxynol 9, propylene glycol, propylparaben, purified water, tea tree oil, trolamine	
<b>Questions</b> 800.835.2263	

Manufactured for:  
**Acme United Corporation**  
 55 Walls Dr, Fairfield, CT 06824  
[www.FirstAidOnly.com](http://www.FirstAidOnly.com)  
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 90594-revA



**Burn Spray**  
 Pain relieving spray  
 for use on minor burns,  
 Lidocaine HCL 2%



2 FL OZ (59 ml)

**FIRST AID ONLY BURN MIST**

lidocaine hydrochloride spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-5750(NDC:59898-201)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
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<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>OCTOXYNOL 9</b> (UNII: 7JPC6Y25QS)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5750-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/13/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2018	

**Labeler** - Acme United Corporation (001180207)

**Registrant** - Acme United Corporation (001180207)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5750) , repack(0924-5750)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5750) , repack(0924-5750)

Revised: 1/2019

Acme United Corporation