

**BURN RELIEF- lidocaine hci 2.0% spray**  
**Trifecta Pharmaceuticals USA, LLC.**

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**Burn Spray**

***Active Ingredient***

Lidocaine HCl 2.0%

***Purpose***

Topical Pain Relief

Temporary pain relief associated with minor burns.

**Warnings**

**For External Use Only**

***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 the reach of children***

If swallowed, 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

***Directions***

- Spray an even layer of burn spray over cleaned affected area not more than 3-4 times daily.
- Not to be used on children under 12 years of age.

***Other information***

- Store at controlled room temperature 68°-77°F (20°-25°C)

***Inactive Ingredients***

Glycerin, hydroxypropyl methylcellulose, melaleuca alternifolia (tea tree) leaf oil, octoxynol 9, PEG-40 hydrogenated castor oil, phenoxyethanol propylene glycol, triethanolamine, water

## Questions or Comments

Call 1-888-296-9067

### ***Distributed By:***

**Trifecta Pharmaceuticals USA, LLC.**

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

**www.trifecta-pharma.com**

**SKU: 4049**

# LABEL

 <b>Burn Spray</b> <b>LIDOCAINE HCl 2.0%</b> Temporary Pain Relief of Minor Burns Net Wt. 2 fl. oz. (59.1 mL) <b>TOPICAL PAIN RELIEF</b>	NDC: 69396-107-02			
	<b>Drug Facts</b> <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Lidocaine HCl 2.0%</td><td>Topical pain relief</td></tr></tbody></table> <p><b>Uses</b> Temporary pain relief associated with minor burns</p> <p><b>Warnings</b> 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 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.</p> <p><b>Directions</b> ■ spray an even layer of burn spray over cleaned affected area not more than 3-4 times daily ■ not to be used on children under 12 years of age</p> <p><b>Other information</b> Store at 68°-77°F (20°-25°C)</p> <p><b>Inactive ingredients</b> glycerin, hydroxypropyl methylcellulose, melaleuca alternifolia (tea tree) leaf oil, octoxynol 9, PEG-40 hydrogenated castor oil, phenoxethanol, propylene glycol, triethanolamine, water</p> <p><b>Questions or comments?</b> Call 1-888-296-9067</p>	Active ingredient	Purpose	Lidocaine HCl 2.0%
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	 8 50026 39349 1 Distributed by: Trifecta Pharmaceuticals USA 101 NE Third Avenue, Suite 1500 Ft. Lauderdale, FL 33301 USA www.trifecta-pharma.com Reorder No. 4049			

**BURN RELIEF**

lidocaine hci 2.0% spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-107
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 g in 1 L

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>OCTOXYNOL-9</b> (UNII: 7JPC6Y25QS)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69396-107-02	0.0591 L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2022	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	07/28/2022	

**Labeler** - Trifecta Pharmaceuticals USA, LLC. (079424163)

Revised: 1/2024

Trifecta Pharmaceuticals USA, LLC.