

## **LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride liquid**

### **Provision Medical**

*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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### **Drug Facts**

#### **Active ingredients**

Lidocaine HCl 2.0%

#### **Purpose**

Topical pain relief

#### **Uses**

Temporary pain relief for 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 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**

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

#### **Inactive ingredients**

aloe vera, germaben II, propylene glycol, purified water

### **Principal Display Panel - 2 fl. oz Bottle Label**

The **Provision**  
First Aid  
Line™

**First Aid**  
**Burn Spray**

**For Temporary**  
**Pain Relief of**  
**Minor Burns**

2 fl. oz. (59.1 ml)

Reorder no. 3500



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Made for Provision Medical Products, LLC, Indio, CA 92211  
1-888-602-0288

## LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69103-5100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>Lidocaine Hydrochloride</b> (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	18 g in 1 L
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### Inactive Ingredients

Ingredient Name	Strength
<b>aloe vera leaf</b> (UNII: ZY81Z83H0X)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>diazolidinyl urea</b> (UNII: H5RIZ3MPW4)	
<b>water</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-5100-0	0.118 L in 1 BOTTLE; Type 0: Not a Combination Product	07/25/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/25/2022	

**Labeler** - Provision Medical (036936831)

### Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-5100)

Revised: 11/2013

Provision Medical