

**LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride liquid**  
**Safetec of America, Inc.**

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**61010-5100, Burn Spray**

***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

Manufactured by **SAFETEC OF AMERICA, Inc.**

Buffalo, NY 14215 800-456-7077 [www.safetec.com](http://www.safetec.com)

**PAIN RELIEF - Burn Spray**

Safetec of America

**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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**PRINCIPAL DISPLAY PANEL - 3 oz. bottle**

NDC 61010-5100-3


Safetec

First Aid  
Burn Spray

For Temporary  
Pain Relief of  
Minor Burns

3 fl. oz. (88.7 ml)

Reorder no. 50104

NDC 61010-5100-4		<b>Drug Facts</b>				
First Aid	Burn Spray	<table border="1"><thead><tr><th data-bbox="824 1014 1073 1052">Active ingredients</th><th data-bbox="1333 1014 1458 1052">Purpose</th></tr></thead><tbody><tr><td data-bbox="824 1052 1268 1083">Lidocaine HCl 2.0%.....</td><td data-bbox="1268 1052 1458 1083">Topical pain relief</td></tr></tbody></table>	Active ingredients	Purpose	Lidocaine HCl 2.0%.....	Topical pain relief
Active ingredients	Purpose					
Lidocaine HCl 2.0%.....	Topical pain relief					
For Temporary Pain Relief of Minor Burns	2 fl. oz. (59.1ml) Reorder no. 50004	<b>Uses</b> Temporary pain relief for minor burns				
		<b>Warnings</b> For external use only <b>Do not use</b> ■ in large quantities, particularly over raw or blistered areas ■ near eyes, if this happens rinse thoroughly with water <b>Stop use and ask a doctor</b> if condition worsens or persists for more than 7 days or clears up and returns <b>Keep out of reach of children.</b> If swallowed get medical help or contact Poison Control Center right away				
		<b>Directions</b> ■ 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				
		<b>Inactive ingredients</b> aloe vera, germaben II, propylene glycol, purified water				
		Manufactured by <b>SAFETEC OF AMERICA, Inc.</b> Buffalo, NY 14215 800-456-7077 www.safetec.com				

**PRINCIPAL DISPLAY PANEL - 2 oz. bottle**

NDC 61010-5100-4

Safetec

First Aid  
Burn Spray  
For Temporary  
Pain Relief of  
Minor Burns  
2 fl. oz. (59.1 ml)  
Reorder no. 50004

NDC 61010-5100-3	
<b>First Aid Burn Spray</b>	
For Temporary Pain Relief of Minor Burns	
3 fl. oz. (88.7ml) Reorder no. 50104	

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Lidocaine HCl 2.0%.....	Topical pain relief
<b>Uses</b> Temporary pain relief for minor burns	
<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 ■ <b>Keep out of reach of children.</b> If swallowed get medical help or contact Poison Control Center right away	
<b>Directions</b> ■ 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	
<b>Inactive ingredients</b> aloe vera, germaben II, propylene glycol, purified water	

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**PRINCIPAL DISPLAY PANEL - 4 oz. bottle**

NDC 61010-5100-5  
Safetec  
First Aid  
Burn Spray  
For Temporary  
Pain Relief of  
Minor Burns  
4 fl. oz. (118 ml)  
Reorder no. 50005

NDC 61010-5100-5



First Aid

# Burn Spray

For Temporary  
Pain Relief of  
Minor Burns

4 fl. oz. (118ml)  
Reorder no. 50005

### Drug Facts

Active ingredients	Purpose
Lidocaine HCl 2.0%.....	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

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## LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61010-5100
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<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:61010-5100-4	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/02/2011	
2	NDC:61010-5100-5	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/02/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	08/02/2011	

**Labeler** - Safetec of America, Inc. (874965262)

## Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(61010-5100)

Revised: 2/2024

Safetec of America, Inc.