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

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61010-5100, Burn Spray

**Drug Facts** 

#### **Active ingredients**

Lidocaine HCI 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

## **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



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

NDC 61010-5100-4

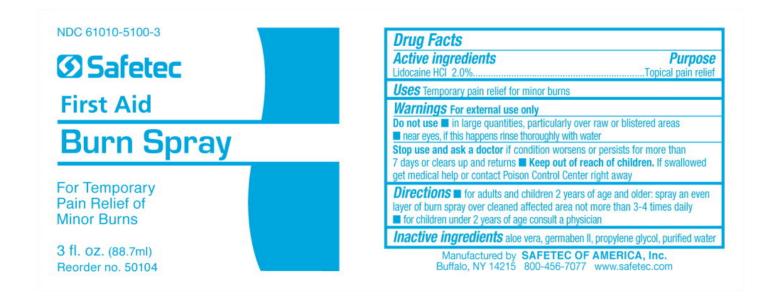
Safetec

First Aid Burn Spray

For Temporary Pain Relief of Minor Burns

2 fl. oz. (59.1 ml)

Reorder no. 50004



#### 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

**Safetec** 

**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

Manufactured by **SAFETEC OF AMERICA, Inc.**Buffalo, NY 14215 800-456-7077 www.safetec.com

#### LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride liquid

#### **Product Information**

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

## **Active Ingredient/Active Moiety**

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

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
WATER (LINII: 0590F0KOOR)			

Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:61010- 5100-4	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/02/2011	
:	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.