LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride liquid
Wildman Business Group

84269-3500, 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

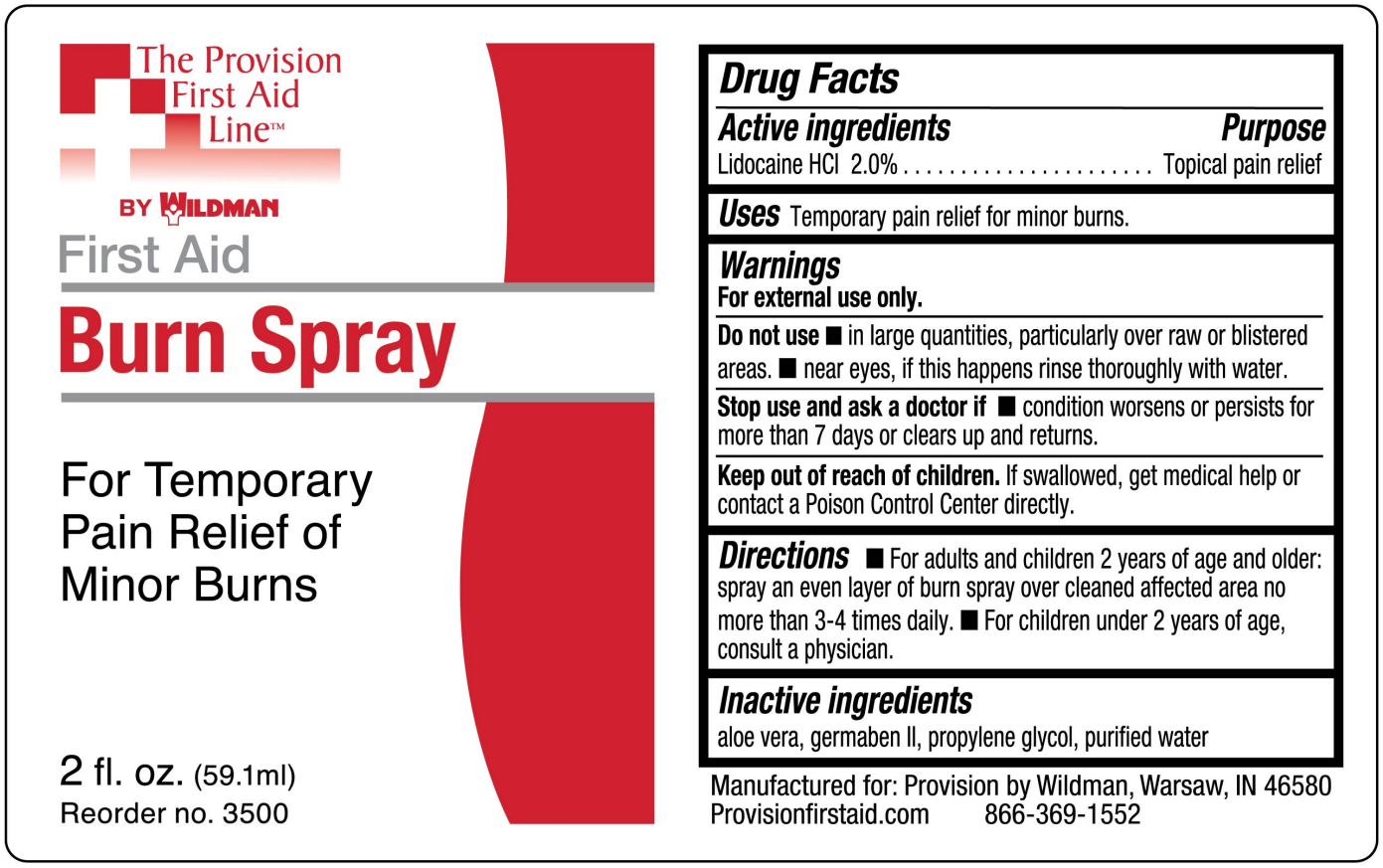
Manufactured by **SAFETEC OF AMERICA, Inc.**

Buffalo, NY 14215 800-456-7077 www.safetec.com

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.

PRINCIPAL DISPLAY PANEL – 2 oz. bottle



Provision

First Aid
Burn Spray

For Temporary
Pain Relief of
Minor Burns

2fl. oz. (59.1ml)

Reorder no. 3500

LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:84269-3500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84269-3500-1	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/01/2024	

Labeler - Wildman Business Group (016677338)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	manufacture(84269-3500)

Revised: 9/2024 Wildman Business Group