

FIRST AID BURN- lidocaine hydrochloride spray

Unishield

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.

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

Questions?

call 1-800-480-5855

Principal Display Panel - 59.1 mL Bottle Label

UniShield

FIRST AID
BURN

SPRAY

For Temporary
Pain Relief of
Minor Burns

NET CONTENTS 2 FL.OZ. (59.1 ML)

Distributed by: UniShield, San Fernando, CA 91340
Made in USA

UniShield
FIRST AID BURN SPRAY
For Temporary Pain Relief of Minor Burns

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FIRST AID BURN

lidocaine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49314-5100
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 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49314-5100-4	59.1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/07/2019	

Labeler - Unishield (790677053)

Revised: 10/2019

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