LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride spray Cintas First Aid & Safety

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.

Burn Spray

Pain Relief

Drug Facts

Active Ingredient

Lidocaine HCl 2.0%

Purpose

Topical pain relief

Uses

for the temporary pain of relief associated with minor burns

Warnings

For external use only

Do not use in large quantities, particularly over raw surfaces or blistered areas

• near eyes, if this happens rinse thoroughly with water

Stop use and ask doctor if

- condition worsens
- symptoms persist for more than 7 days
- condition clears up and occurs again within a few days

Keep out of reach of children. If swallowed get medical help or contact Poison Control Center right away.

Directions

- adults and children 2 years of age and older: to affected area not more than 3-4 times daily
- children under 2 years: consult a doctor

Other information

store at room temperature

Inactive ingredients

aloe vera, germaben II, propylene glycol, purified water

Questions or Comments?

PRINCIPAL DISPLAY PANEL - 2 oz. bottle

BURN SPRAY

LIDOCAINE HCl 2%

Convenient pump spray allows no-touch application. Use as a first aid treatment for minor burns, scalds & sunburn. Water-soluble.

2 fl. oz. (59.1 mL)

Xpect First Aid



LIDOCAINE HYDROCHLORIDE lidocaine hydrochloride spray Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68421-5100

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Danta	Λŧ	minic	stration

TOPICAL

	Active	Ingredient/Active	Moietv
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ı	Active ingredient/Active words		
l	Ingredient Name	Basis of Strength	Strength
I	Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	20 g in 1 L

Inactive Ingredients

Ingredient Name aloe vera leaf (UNII: ZY8 1Z8 3H0 X) propylene glycol (UNII: 6DC9 Q 16 7 V 3) diazolidinyl urea (UNII: H5RIZ3MPW4)	inactive ingredients				
propylene glycol (UNII: 6DC9Q167V3)	Ingredient Name	Strength			
	aloe vera leaf (UNII: ZY8 1Z8 3H0 X)				
diazolidinyl urea (UNII: H5RIZ3MPW4)	propylene glycol (UNII: 6DC9Q167V3)				
water (UNII: 059QF0KO0R)	water (UNII: 059QF0KO0R)				

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68421-5100- 0	0.0591L in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	04/18/2013		

Labeler - Cintas First Aid & Safety (056481716)

Registrant - Safetec of America, Inc. (874965262)

Establishment			
Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(68421-5100)

Revised: 4/2013 Cintas First Aid & Safety