

LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride liquid

Afasco Inc.

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 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 a 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

PRINCIPAL DISPLAY PANEL – 2 oz. bottle

Burn

Spray

External Analgesic

- Relieves Pain Fast
- Washes Off Easily

#610 2 Fl. Oz. (59 mL)

Mfd. For
Afassco
MINDEN, NV 89423

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LIDOCAINE HYDROCHLORIDE			
lidocaine hydrochloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-6101
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride	200 mL in 1 L
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:51532-610 1-2	0.059 L in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/16/2012	

Labeler - Afassco Inc. (609982723)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(51532-6101)

Revised: 7/2012

Afassco Inc.